

Centers for Disease Control

Center for Global Health Extramural Research Program Office

Advancing Public Health Research in Central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama)
RFA-GH-18-004
Application Due Date: 03/09/2018

Signature _____ Date _____

Advancing Public Health Research in Central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama)

RFA-GH-18-004

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

Center for Global Health Extramural Research Program Office (CGH ERPO)
Center for Global Health (CGH)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
National Center for Immunization and Respiratory Diseases (NCIRD)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)
Office of Infectious Diseases (OID)
Office of Public Health Preparedness and Response (OPHPR)

Notice of Funding Opportunity (NOFO) Title

Advancing Public Health Research in Central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama)

Activity Code

U01- Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-GH-18-004

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

93.326

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this cooperative agreement is:

- To conduct and monitor epidemiologic, clinical, and laboratory-based projects, surveillance, and research of important human diseases in Central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama) including but not limited to acute febrile illness, antimicrobial resistance and hospital acquired infections, respiratory infections and influenza, enteric illnesses, and other public health threats.
- To incorporate the results of research activities into operational disease detection, prevention, and response or control programs in the Central American Region and ensure increasing local workforce capacity and sharing of findings across the region and with partners.

Other areas for research include emerging and re-emerging infectious diseases, zoonotic and vector borne diseases, environmental health issues effecting infectious diseases such as water and air), neglected tropical diseases, maternal and child health, birth defects and developmental disabilities, vaccine- preventable diseases, bio-safety, injury control and prevention, and other

public health threats of local importance.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-GH-18-004, 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:	**02/08/2018**
Application Due Date:	**03/09/2018**

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

Scientific Merit Review:	**04/09/2018**
Secondary Review:	**05/07/2018**
Estimated Start Date:	**09/15/2018**
Expiration Date:	**03/09/2018**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this 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.

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

Executive Summary

The purpose of this Notice of Funding Opportunity (NOFO) is: to conduct and monitor epidemiologic, clinical, and laboratory-based projects, surveillance, and research of important human diseases in Central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama) including but not limited to acute febrile illness, antimicrobial resistance and hospital acquired infections, respiratory infections and influenza, enteric illnesses, and other public health threats; to incorporate the results of research activities into operational disease detection, prevention, and response or control programs in the Central American Region and ensure increasing local workforce capacity and sharing of findings across the region and with partners; and, to include other areas for research such as emerging and re-emerging infectious diseases, zoonotic and vector borne diseases, environmental health issues, neglected tropical diseases, maternal and child health, birth defects and developmental disabilities, vaccine-preventable diseases, bio-safety, injury control and prevention, and other public health threats of local importance.

• Mechanism of Support: Cooperative Agreement

• Funds Available and Anticipated Number of Awards: The estimated total funding available, including direct and indirect costs, for the entire or 5 year project period is $45,000,000. The number of awards will be up to seven (7). 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 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 budget of the applications received.

• Budget and Project Period:
- Budget Period- 9/15/2018- 9/14/2019.
- Project Period- 9/15/2018- 9/14/2023.

• The estimated total funding (direct and indirect) for the first year (12-month budget period) will be $5,000,000 with individual awards ranging from $100,000 to $500,000 for the first year. The estimated total funding (direct and indirect) for the entire project period will be $45,000,000. The project period is anticipated to run from 9/15/2018 to 9/14/2023.

• 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 of this announcement 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. There will only be one (1) PD/PI for each application.

• Number of Applications. Only one (1) application per institution (normally identified by having a unique DUNS number) is allowed.

• Application Type. New.

• Special Date(s). Applicant Call- January 17, 2018 at 1:00pm Central America. Phone number: 1-866-6924538, passcode: 69443761#.

• Application Materials. See Section IV.1 for application materials. Please note that Form E is to be used when downloading the application package.

• Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 307 of the Public Health Service Act [42 USC 242l], as amended and Section 301(a) of the Public Health Service Act [42 USC 241(a)], as amended.

1. Background and Purpose

The Central America Region is comprised of Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and the Dominican Republic. The population of 54.8 million people is divided unequally, with 350,000 people living in Belize at the low end and 14.9 million in Guatemala at the highest population level. The region has a substantial rural population that is becoming more urbanized. Every country in the region is classified as a low or upper-middle income country by the World Bank.

Despite progress made in the last decade, Central America and the Dominican Republic are characterized by deep social inequalities, with large segments of the population living in vulnerability and exclusion, limited access to health, education, housing and employment. Access to improved water supply is generally high, but access to improved sanitation is as low as 36% in Guatemala. Persons below average weight (underweight) is an ongoing issue in most Central American countries. However, birth rates are typical for middle-income countries. Central American health systems are highly fragmented, and as a result, there is low quality of care for much of the population, inefficient use of resources, and a high burden (of disease).

In addition to urbanization, the population of Central American nations are quite mobile; people are often moving between and through countries in the region. In addition to high numbers of visitors and legal immigrants to the United States, in recent years, violence, poverty, and other social stressors have resulted in highly-publicized illegal migration.

Infectious diseases such as influenza, Chagas' disease, leptospirosis, Chikungunya, Zika, malaria, typhoid fever, rabies, and many others are endemic in all or part of Central America. Challenging geography, poor infrastructure, and weak health systems increase Central Americans risks of severe morbidity and mortality from those infections. Limited capacity to detect and identify pathogens causing syndromes such as Acute Febrile Illness (AFI) results in limited surveillance and knowledge of the burden of various health threats. National governments in Central America do not have the information needed to prioritize scarce resources; and, interventions to prevent and control diseases of significance in the region are

lacking in many areas.

The Centers for Disease Control and Prevention (CDC), Central America Regional Office's mission is to protect and promote health in the region through collaboration with partners on science, policy, and evidence-based public health actions, thereby improving global health security. The CDC Central America Regional Office works in close partnership with governments in the region, as well as other local, national, and international partners to improve the understanding and prevention of disease, and to improve the region's health systems, and epidemiologic and laboratory capacity to study and prevent diseases. Building such public health capacity in partner countries for public health science, surveillance, laboratory expertise and implementation of prevention measures and rapid response to disease threats through collaborative efforts will impact the health and well-being of people around the world and keep Americans safe and healthy.

The goal of this NOFO is to:
1. Study and report on the epidemiology, transmission and causes of infectious agents and their vectors in the Central American Region with an aim to understand trends and detect common pathogens of public health relevance;
2. Conduct research studies on the epidemiology and risk factors of agents for illness, hospitalization, and death in the population as a whole, and in vulnerable populations;
3. Improve capacity to detect the range of infectious organisms in the region through surveillance, response, and laboratory expertise including assessment of new modalities and approaches;
4. Assess effectiveness and evaluate programs of prevention, control, and treatment measures in the region;
5. Understand risk factors for, and burden of, disease caused by environmental hazards (such as toxins), and other diseases of interest in the region in order to inform the development and implementation of potential interventions; and,
6. Assess prevention measures and potential environmental factors (water, air, vectors) interacting with infectious disease for conditions of interest to the region.

Healthy People 2020 and other National Strategic Priorities

While Healthy People 2020 is not applicable, this NOFO aligns with other national and current CDC strategic priorities including: strengthening surveillance, epidemiology and laboratory services; supporting public health activities; evaluating public programs; conducting operational research; increasing global health impact; increasing impact on public health policy; preventing illness, injury disability and death; and ensuring Global Health Security through understanding and preventing global health threats before they occur and minimizing those threats nationally, regionally and globally.

As continued progress in public health preparedness is challenged by the current economic times, an eroding public health infrastructure worldwide, and the ever increasing threat of bioterrorism and emerging infectious diseases, applications funded under this NOFO will have a positive impact and reduce the burden on public health resources by addressing the following CDC strategic priorities and initiatives for the broader public health community.
1. Prevent and mitigate threats to the public health of the global community by increasing public health involvement in national and global health security efforts and advancing the ability to measure and address gaps in public health preparedness.

2. Advance surveillance, epidemiology, and laboratory science through the integration of public health preparedness and response data, reporting systems and processes, and increasing the effectiveness of surveillance, epidemiology, and laboratory science research through the application of novel approaches using advanced equipment, modeling approaches, and public health tools.
3. Strengthen public health preparedness and response infrastructure through the development of sustainable public health system capacities (e.g., laboratory, communications, health information, emergency operations centers, response and support staff, and information technology infrastructure) for preparedness and response, and continuously assessing the adequacy of these systems and associated infrastructure.
4. Increase the application of public health science to preparedness and response practice by expanding knowledge that contributes to the reduction/mitigation of threats to the public's health, and through the development of tools and promising practices, to improve public health preparedness and response practice.
5. Improve the ability of the public health workforce to respond to health threats by enhancing public health preparedness and response workforce competencies.

Public Health Impact

The Central America Region is home to 54 million people at risk of severe disease from common illnesses, and at risk for emerging and re-emerging infectious diseases and other health threats. Understanding the spectrum of etiologies of clinical syndromes, risk factors for infection and severe disease, and the effectiveness and advantages of prevention and control programs is key to advancing public health in this region. The intention of the NOFO is to provide a positive health impact through conducting excellent public health research in infectious and non-infectious diseases that can guide stakeholders to prioritize resources and implement health practices and policies to mitigate the impact of health threats on the population. Through better understanding of disease threats, and their control and prevention, morbidity and mortality may be lowered, and global health security increased.

Relevant Work

CDC has worked in Central America for more than 40 years. The goal of the work continues to be to develop and strengthen systems that enable the countries in the region to identify and respond to emerging infections. CDC coordinates with local, regional, and global public health entities to rapidly detect, accurately identify, and promptly contain emerging disease threats. Collaborations with regional partners have yielded important data on the burden of a broad range of infectious diseases, detection of poorly understood and novel pathogens, as well as causes and rates of mortality in the populations under surveillance. As a result of these collaborative efforts, there comes a strengthening the Ministries of Health (MOHs) public health capacity, primarily in collaboration with Departments of Epidemiology and Surveillance, the National Laboratories, the National Public Health Institutes, and other specific disease control programs.

CDC has several activities that support or relate specifically to this NOFO. Prospective applicants should refer to the following websites and related documents for additional

information:

http://www.cdc.gov/globalhealth

http://www.cdc.gov/globalhealth/gdder/gdd

http://www.cdc.gov/globalhealth/gdder/who

http://www.cdc.gov/globalhealth/ihregulations.htm

http://www.cdc.gov/globalhealth/ghi

http://www.cdc.gov/globalhealth/ghi/pdf/GHIStrategy.pdf

https://www.cdc.gov/flu/international/program/index.htm

2. Approach

Objectives/Outcomes

Applicants must propose activities that support or develop surveillance, public health–related research studies, and/or research activities that will promote, coordinate, and support technical aid activities. Research activities should be focused on the detection, prevention, response, and elimination of communicable diseases, zoonosis, and other emerging public health threats in the Central American Region.

Disease Areas

Applicants may focus their application on one or more of the following eligible disease areas:

1. Acute febrile illness
2. Antimicrobial resistance (AMR) and/or hospital acquired infections (HAI) (i.e. nosocomial or health care acquired infections)
3. Respiratory illness and influenza
4. Enteric illnesses
5. Other public health issues of regional and local importance

PROJECT CATEGORIES

Applicants must propose activities that focus on the disease area(s) selected in at least one of the following project categories. Examples of activities are provided under each project category:

Category A: Surveillance Projects

Include conducting community or population-based surveillance research projects that will result in sustainable and scalable surveillance systems to produce evidence that guides public health interventions. Methods such as for innovative and improved pathogen detection and characterization or other methods are encouraged. Examples of surveillance projects are:

- Develop, maintain, or expand one or more surveillance systems in the Central American Region combining population-based and facility-based demographic, morbidity, and mortality surveillance designed to determine burden of disease, transmission dynamics, risk factors and control of infectious and toxic agents. A

multi-site system could include population/site diversity with regard to urban/rural, geography within or between countries, socioeconomic factors, etc.
    - Support the development of laboratories and/or platforms used for etiologic investigation, evaluation of novel diagnostic assays for faster and easier detection, and characterization of pathogens, including point-of-care diagnostics.
    - Develop, maintain and expand sentinel surveillance systems.
    - Identify methods to improve efficiency, coverage, and quality of hospital-based laboratory confirmed disease surveillance in representative hospitals and outpatient clinics in the Central America Region.
    - Conduct ongoing and systematic collection, analysis and interpretation of biological samples and data for both animal and human health in collaboration with Ministries of Health and Agriculture of Central America in order to strengthen surveillance at national and regional levels.
    - Develop and further implement diagnostic tests for identification and characterization of pathogens.

Category B. Research Studies of Risk Factors, Burden, and/or Transmission Projects

Include conducting research activities to identify modifiable risk factors for priority diseases through community and/or population-based observational or experimental research. Also included are research on disease burden, transmission or other factors related to risk. Research findings should be presented at international meetings and published in the peer-reviewed literature. Examples of risk factor and associated research studies are:

- Conduct research to determine burden of morbidity and mortality, transmission dynamics, risk factors, and control of infectious and toxic agents in the Central American Region.
- Conduct active surveillance and laboratory confirmation of pathogens to assess disease burden and the relative contribution of viral infections during pregnancy to the health and development of young children through utilizing an existing cohort.
- Develop and implement research of existing and archived specimens in order to answer questions of public health importance.
- Conduct qualitative socio-cultural research and surveys of knowledge, attitudes, and practices related to infectious disease and the acceptance of methods of prevention.
- Estimate the relative contribution of different pathogens to disease syndromes to understand burden of disease and guide resource utilization.
- Develop and/or maintain one or more clinical research sites to investigate and report the interactions between specific pathogens and underlying comorbidities.
- Conduct research on the human-animal interface of zoonotic diseases and risks of transmission from animals to humans.
- Provide innovative solutions identified through research to develop early warning systems to report sentinel organisms in humans that can serve as an alert for multidrug resistant organisms and interventions for adequate antimicrobials.

Project Category C -Effectiveness Research

Includes research on interventions to prevent and control diseases of importance in the Central

American Region. These projects might use various designs and sources of data. The findings should be used to guide the development and/or improvement of national and regional policies and programs for disease prevention, monitoring and control. Examples of effectiveness research are:

- Develop cost of disease estimates and cost effectiveness estimates of priority diseases.
- Conduct operational research on public health program implementation and approaches to outbreak investigations, surveillance, and emergency preparedness and response.
- Conduct evaluations of vaccine programs in the Central America Region to determine coverage rates, barriers, best practices, and effectiveness.
- Conduct research to assess efficacy/effectiveness, immunogenicity and impact of vaccines, treatments, and non-pharmaceutical interventions and other control measures to reduce the burden of influenza disease among vulnerable populations.
- Conduct a systematic review of AMR/HAI activities in the Central American Region. This includes the development of a catalogue of research and public institutions working in AMR/HAI to include information on location, description of activities, populations served, and a summary of relevant publications in the last 5 years.

Conduct research to estimate the direct and indirect costs, and document the economic burden of priority diseases and interventions.

Target Population

The target populations for this NOFO are those who are representative of the Central American Region in general, and/or are in high risk groups, such as pregnant women, children, low income persons, rural and/or urban informal housing populations.

Collaboration/Partnerships

Applicants are expected to develop and maintain collaborations with key regional organizations, including but not limited to, the Pan-American Health Organization (PAHO), Consejo de Ministros de Salud de Centroamérica y República Dominicana (COMISCA), and research institutions.

Applicants must show evidence of support from Ministries of Health or other ministries as appropriate in any country in which activities are proposed.

Applications must include plans to involve local collaborators and improve local workforce capacity in design, conduct, data analysis and interpretation, and development of written research products (reports, manuscripts, presentations, etc.).

Applicants must develop and maintain collaborations with the Ministries of Health in the countries in which they work and with associated organizations for the execution of proposed activities. Projects must include plans for supporting the use of research findings by Ministries of Health.

Consortia of research institutes, health organizations and other relevant parties are encouraged but not required.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims within the research project period. The awardee will establish specific, measurable, achievable, realistic, and time-phased (SMART) project objectives for each activity described in the applicant's project plan, and develop and implement project performance measures that are based on specific programmatic objectives.

Translation Plan

The Applicant should describe plans for how research and scientific findings will be reported and disseminated (e.g., peer-reviewed journals, scientific presentations, reports, meetings and conferences) and specify how these activities are integrated into the project plans. The translation of findings should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, health care institutions, professional organizations, community groups, researchers, and other potential users.

Questions to consider in preparing this section include:

1. How will the scientific findings inform governments in the Central American Region as well as, other stakeholders on needed public health policies or practices at the country and regional level
2. How will the research project improve or affect the translation of study findings into policy or practice?
3. How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs and practices?
4. How will the research findings advance or guide future scientific efforts or related activities?
5. How will the research activities improve public health outcomes, advance workforce development, and enhance response capacity?

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: $45,000,000

Year 1: $5,000,000

Year 2: $10,000,000

Year 3: $10,000,000

Year 4: $10,000,000

Year 5: $10,000,000

Anticipated Number of Awards: 7

Throughout the project period, CDC's commitment to continuation of awards will be conditional on 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.

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

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

Award Ceiling: $45,000,000 Per Project Period

Award Floor: $100,000 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 (https://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:

Public and State controlled institutions of higher education
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm DUNS by sending an e-mail to ccrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf.

Foreign components of U.S. Organizations are eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Experience working with ministries of health, academic institutions, and other public health organizations in countries where activities are proposed (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, or Panama).

Applicants must demonstrate experience working with ministries of health, academic institutions, and other public health organizations in countries where activities are proposed (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, or Panama).

4. Justification for Less than Maximum Competition

Not Applicable

5. Responsiveness

Any application that does not fully respond to the items in this section will be deemed "nonresponsive" and will not be moved forward for scientific peer review.

1. Applicant must have submitted an LOI received by the due date of LOI
2. Applicant can apply in more than one project area, but cannot apply in more than 2 Project Categories (A, B, C).
3. The application must specify disease topic areas to be covered by the activity, the Project Category (A, B, or C), countries where the activities will be conducted, and be within the scope of objectives described.
4. Applicants cannot apply to conduct any single activity in more than two countries in Year 1, but can propose the activity in >2 countries in subsequent years. For example, an applicant can propose to begin a surveillance project of AFI risk factors in El Salvador and Belize in Year 1, and add Costa Rica and Dominican Republic in Year 2.
5. Applicant should not exceed budget limit specified in Year 1.
6. Applicant must include a list of investigators who will be involved in the project, their roles, and qualifications for their proposed roles.
7. Applicant must demonstrate experience in working with scientific partners on public health science and animal health activities in the countries where they propose to have activities. This

experience might be shown through listing publications and/or project summaries.
8. Applicant must provide letters of support from the Ministry of Health, and Ministry of Agriculture when applicable, in the countries where work activities are proposed
9. For each application, applicant must provide a cover letter on institution letterhead that summarizes and details the activities applied for and the proposed funding level for the activities.

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%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.
All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

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

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

which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the 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.

One application per institute.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.
If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.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 forms package associated with this NOFO includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/funding/424/index.htm.

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 in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

3. Letter of Intent

Due Date for Letter of Intent: **02/08/2018**
A letter of intent is mandatory for this NOFO. The information that it contains allows CIO staff to estimate the potential review workload and plan the review.

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

Name of the Applicant

Descriptive title of proposed research

Applicant should state which component they are applying to

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

Names of other key personnel

Participating institutions

Number and title of this funding opportunity announcement

The letter of intent should be sent to:

Lata Kumar

Extramural Research Program Office

Office of the Associate Director of Science

Center for Global Health

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS D-69

Atlanta, GA 30333

Telephone: 404-639-7618

Fax: 404-639-7490

Email: lkumar@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.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Notices of Funding Opportunities(NOFOs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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 (R&R) 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 timeline.
4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)
5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table (for New Application ONLY)
9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the NOFO. 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: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for 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 archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

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.

Projects under each category should be include all the Research plan components. Applicants submitting more than one project should add the title and submit this under the Appendix section to accommodate space and submission issues in the package.

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 75 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.
CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf
and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged

to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.
Organizations must submit applications via Grants.gov (https://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.
If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.
Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.
Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).
Information on the submission process is provided in the SF424 (R&R) Application Guide.
Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window). The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.
Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.
After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, ***the applicant*** must:
1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the NOFO (ogstims@cdc.gov) explaining why the submission failed. b. If there is time

before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **03/09/2018**

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)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

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.

Restrictions, which must be taken into account while writing the budget, are as follows:
• Recipients can only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.

• The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
• Reimbursement of pre-award costs is not allowed.
• Indirect Costs: for US based organizations, the standard indirect cost rate applies, based on current, federally negotiated indirect cost rate agreement. For foreign organizations, the regulation has recently changed to allow for indirect costs; however, implementation and calculation of these costs has not been finalized. If a foreign based organization is approved for funding and requests indirect costs in their budget, these costs will be defined and calculated during budget discussion.
• All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign awardees for currency exchange fluctuations through the issuance of supplemental awards.
• Foreign grantees are subject to audit requirements consistent with 45 CFR 75, Subpart F, and as will be further specified in their notices of award. A non-federal audit is required, if during the awardees fiscal year, the awardee expended a total of $300,000.00 or more under one or more HHS awards (as a direct grantee and/or as a sub-grantee). The awardee either might have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the awardee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements contained in OMB Circular A-133.
• A recipient capability assessment or other pre-award assessment might be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities, regarding the handling of U.S. Federal funds. A pre-award assessment will be conducted prior to award to any organization that has never received US Federal Funds.
• If research involves human subjects, funds will be restricted until a Federal Wide Assurance (FWA) and Institutional Review Board Approvals (IRB) are in place.

OMB Requirements

The Office of Management and Budget (OMB) requires that all projects in which CDC staff will provide technical assistance or advice on any information collections on 10 or more people that are planned or conducted by the awardee, all such information collections – where CDC staff will be or are approving, directing, conducting, managing, or owning data – must undergo OMB project determinations by CDC and might require OMB PRA clearance prior to the start of the project.

•On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements.

• Non-compliance with this Policy might result in suspension, limitation, or termination of USG funding, or loss of future US Government (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 might subject the institution to other potential penalties under applicable laws and regulations.
• 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 can 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 applications for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
• 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.

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**
Applicants must complete all required registrations before the application due date.
Section III.6 "Required Registrations" contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

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

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the

Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.
See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding _errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm
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), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

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

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

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

• Does the applicant understand the objectives of this cooperative agreement program?
• Does the work address a scientific problem of great importance to public health research and/or practice?
• What is the potential or actual impact of the research on public health in the US and/or globally?
• Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?

• If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk?

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?

• Are the investigators or collaborators based in countries of the proposed study sites?
  - Or does their institution have an established track record of ongoing research or programmatic work in the proposed countries?
• Do the investigators have a successful track record in public health research?
• Is there evidence of past collaborations with the proposed research team?
• Does the applicant understand the roles and responsibilities of participation in the program (GDD)?
• Does the investigators' training and experience match the requirements carry out this work?
• Is the work proposed appropriate to the experience level of the principal investigator and other researchers?
• Does the investigative team bring complementary and integrated expertise to the project?
• Has the applicant identified key professional personnel for assignment to the proposed research and network projects?
• Has the applicant identified key professional personnel from other participating or collaborating institutions, agencies, and organizations outside the applicant's agency that will be assigned to activities?
• Is a curriculum vitae provided for each in the appendix?
• Does the applicant clearly state participants' roles in the management and operation of the research agenda?
• Does the applicant provide descriptions of participants' experience in conducting work similar to that proposed in this announcement?
• Does the applicant describe all support staff and services to be assigned to the proposed research?

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 reasonable potential for concrete

applications of interest and value to CDC?
- Does the project have the potential to increase efficiency or lead to cost savings?

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 application propose to use evidence-based interventions or strategies in the research plan?
• Does the evaluation plan identify outputs and are measures/metric to assess outcomes included?
• Does the translation plan describe how the results from the research will be disseminated and ultimately used?
• Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project?
• Is a logic model or equivalent presented as a useful tool for showing the interrelationships of the purpose, outputs and outcomes?
• Does the application include an interagency plan between MOH health and safety programs that defines each agency's responsibilities and support functions and, when appropriate, their active participation in projects as evidenced by collection and submission of data or specimens, or evidence of other specific contributions to projects?
• Are the proposed collaborations between the applicant’s proposed programs and the disease surveillance, laboratory, emergency response or workforce development program appropriate and defined with sufficient detail to be expected to identify projects that provide MOH programs with information assisting them with control of risk factors to illness and outbreaks?
• Does the applicant describe the requirements, responsibilities, problems, constraints, and complexities that might be encountered in implementing and coordinating proposed activities related to surveillance, lab, emergency response and/or workforce development?
• Does the applicant acknowledge potential problem areas and consider alternative tactics?
• Does the applicant describe their plan for establishing and collaborating with other local organizations and Ministries of Health or Ministries of Agriculture?
• Does the applicant succeed in describing the level of involvement that will be provided by each partner?
• Does the applicant provide (in an appendix) letters of support indicating collaborators’ commitments to participate in the projects, and describing their anticipated role?
• Does the applicant describe the ability to conduct research activities that address the needs and characteristics of the proposed countries/region (i.e., demographic or language)?
• Does the applicant clearly identify the proposed organizational and operating structure and procedures for working in the proposed countries and collaborating with Ministries of Health (or other government organizations) and local partners?

• Does the applicant describe the roles and responsibilities of all participating agencies, organizations, institutions, and individuals?
• Does the applicant describe plans to collaborate with CDC? 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?

- Does the applicant describe whether/how the proposed work will relate to other programs sponsored by the agency, which are already in place or planned to support or strengthen disease surveillance, laboratory systems, emergency response and/or workforce development?
- Does the project utilize critical partnerships or collaborations? Does the project support key stakeholder involvement throughout the research process?
- Does the project utilize critical partnerships or collaborations including the Ministry of Health or with laboratory capacity including accredited national reference laboratories?
- Does the applicant have experience in running population-based surveillance?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.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 five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.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.

Applications from Foreign Organizations
Reviewers will assess whether the project presents special opportunities for furthering

research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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:

• Type of data to be produced in the proposed project;

• Mechanisms for providing access to and sharing of the data (including 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; and

• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.

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, 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.
The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.docx

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 all responsive applications 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 decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Investigators responding to this funding opportunity announcement should include a detailed

Data Management Plan (DMP) in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. Reviewers will consider whether the DMP includes: the data to be produced in the proposed project; standards to be used for collected or created data; mechanisms for providing access to and sharing of the data (including 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; and plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.

Funding preference will be given to Applications that include investigators who are residents and citizens of the Central America Region. When making awards, funding decisions will take into consideration geographic and Project Category (A, B, C) diversity. CDC will fund no more

than one project per country, whether it is a single-country or a multiple-country project, until at least 5 countries have been covered. For single- and multiple-project category applications, CDC will fund no more than one project category until all 3 project categories are covered. If additional funding is available, CDC will have the option to fund a second award per country and/or per Project Category.

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 recipient's business official.

Recipients 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. CDC programs must indicate which ARs are relevant to the NOFO. All NOFOs from the Center for Global Health must include AR-35. Recipients must then comply with the ARs listed in the NOFO. Do not include any ARs that do not apply to this NOFO. NOFO 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:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-8: Public Health System Reporting Requirements

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-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR

AR-18: Cost Recovery – ATSDR

AR-19: Third Party Agreements – ATSDR

AR-20: Conference Support

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-23: Compliance with 45 C.F.R. Part 87

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Policy on Public Health Research and Non-research Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

AR-28: Inclusion of Persons Under the Age of 21 in Research

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

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 – FY 2012 Enacted General Provisions

ARs applicable to Global Health Assistance Awards:

AR-35: Protecting Life in Global Health Assistance

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.fsrs.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 recipients 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. Recipients (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.

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 Part 75, 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 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.

The PD(s)/PI(s) will have the primary responsibility for:
•Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
• Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html

The PD(s)/PI(s) will have the primary responsibility for:
• Establishing a program to meet the research objectives described in this Funding Opportunity Announcement.
• Overseeing all management, administrative, and scientific/programmatic aspects of the research including all data, resources and operations.
• Providing the necessary personnel and supplies to implement components and analyze the results.
• Collaborating with local senior researches, CDC researchers and community-based organizations or similar community liaison for the duration of the project period on several activities such as the development of the data-collection instruments, specimen collection protocols, and data-management procedures.
• Working with HHS/CDC scientists to refine protocols to improve the study and other proposal

components based on reviewers 'comments in the summary statement. The awardee will obtain IRB approval for all collaborators.
• Identifying, recruiting, obtaining informed consent from, and enrolling an adequate number of study participants, as determined by the study protocols and the program requirements. The awardee will obtain IRB approval for all collaborators.
• Following study participants as determined by the study protocols.
• Establishing procedures to maintain the privacy of the study participants and confidentiality of the research data. The awardee will obtain IRB approval for all collaborators.
• Obtaining and maintaining the appropriate Institutional Review Board (IRB) or ethical review process approvals for all institutions or individuals participating in research involving human subjects.
• Agreeing to share data and specimens with CDC scientists, as well as appropriate international partners, such as the World Health Organization.
• In collaboration with HHS/CDC, presenting at international meetings and publishing research findings in peer-reviewed scientific journals.
• Participating in conference with HHS/CDC project official(s) and research team; and attend in-person meeting with HHS/CDC co-investigators.
• Collaborating with USG agency scientists to meet objectives of this agreement.
• Meeting the reporting requirements outlined in the Notice of Grant Award.
• Sharing all data and other project and programmatic information with CDC upon request.
• Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access
• Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
• Working with CDC scientists to obtain OMB-PRA approvals, as needed.
• Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
• Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

Publications/ Presentations: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate. For example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC for review, all program abstracts or manuscripts prior to any publication related to this funding. The awardee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.

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.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
• Monitor the cooperative agreement and provide input on its implementation.
• Collaborate with awardee to establish priorities for the development and implementation of the recipient activities, both among and within each of the areas, through regular meetings and communication.
• Collaborate as needed with funded institutions by providing technical assistance in support of activities implemented under this agreement.
• Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses.
• Provide technical assistance to the recipient and linking them with other national and international agencies that might provide additional technical or material assistance.
• Collaborate with the affiliated institutions (funded organizations) in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
• Provide assistance in the development of a research protocol for IRB review by all collaborating institutions that are participating in the research project, including the CDC IRB, if applicable. Obtain and maintain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
• Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses. Based on this, CDC will make recommendations aimed at solving problems and at improving the quality and timeliness of the research activities.
• Support data analysis as required and participate in publication of results.
• Assist in designing, developing, and evaluating methods and pilot studies.
• Assist in the protocol development, implementation, data analysis, interpretation of results, and dissemination of findings and pilot demonstration findings including report writing and oral presentation.
• Collaborate in development of a research protocol for IRB/ethical review by all cooperating institutions that are participating in the research project.
• Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.
• Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access.
• Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
• Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
• Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

The Scientific Program Officer in the CGH Extramural Research Program Office (ERPO) will be

responsible for the normal scientific and programmatic stewardship of the award as described below:
• Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award;
• Serve as the primary point of contact on official award-related activities including an annual review of the awardee's performance as part of the request for continuation application;
• Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
• Carry out continuous review of all activities to ensure objectives are being met;
• Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and • Monitor performance against approved project objectives.

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 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 recipient'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:

Updates to the Data Management Plan (DMP): Include any updates 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.

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 recipient'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)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)
Olga Henao, Country Manager
CGH, Division of Global Health Protection
Telephone: 404-639-3393
Email: dot8@cdc.gov

Loren Cadena
CGH, Division of Global Health Protection
Telephone: 404-639-0603
Email: bqp3@cdc.gov

Peer Review Contact(s)
Hylan Shoob
Extramural Research Program Office
CGH Science Office, Office of the Director
Center for Global Health

CDC
Atlanta, GA 30033
Telephone: 404-639-4796
Email: hylan.shoob@cdc.gov

Financial/Grants Management Contact(s)
Joy Igonikon, Grants Management Specialist
Center for Global Health, Division of Global Health Protection
Telephone: 770-488-2602
Email: jci5@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.

Section III, 8: (Eligibility Requirements).

Concerning the need of individuals in underrepresented racial and ethnic groups (page 14), this language is standard NOFO language. CDC's work in Central America has found that people in the region i.e. smaller NGOs or underrepresented groups should be aware that they could apply for this opportunity.

Section VI - 5.1 (Competing Supplements) New Research Projects Developed during the Cooperative Agreement Period.
After the initial funding in September 2018, any new research projects during years 2-4 will be considered for funding, provided the list of proposed projects is submitted as indicated in Section on IV in the month of January of that year. All new research projects will follow the same guidelines in Section IV, Content and Form of Application Submission. The submission time line would be March 1st of that year. The proposals will be peer reviewed and funding is based on availability of funds. New proposals could be submitted to CGHERPO@cdc.gov

Section VI - 5.B3 (Competing Supplements) New Research Projects Developed during the Cooperative Agreement Period.
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 VI, 6: (Award Administration Information).

Concerning Language Access (pg34), this language is standard NOFO language. CDC is committed, per policy to ensure equal access so that smaller NGOs or underrepresented groups could apply for this opportunity.