

Centers for Disease Control and Prevention

Center for Global Health Extramural Research Program Office

Conducting Operational Research to Identify Numbers and Rates, Determine Needs, and Integrate Services to Mitigate Morbidity and Mortality Among Internally Displaced Persons Affected by Emergencies

RFA-GH-15-008

Application Due Date: 04/20/2015

Conducting Operational Research to Identify Numbers and Rates, Determine Needs, and Integrate Services to Mitigate Morbidity and Mortality Among Internally Displaced Persons Affected by Emergencies

RFA-GH-15-008

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Center for Global Health Extramural Research Program Office (CGH ERPO)
Center for Global Health (CGH)

Funding Opportunity Announcement (FOA) Title

Conducting Operational Research to Identify Numbers and Rates, Determine Needs, and Integrate Services to Mitigate Morbidity and Mortality Among Internally Displaced Persons Affected by Emergencies

Activity Code

U01

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-GH-15-008

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

93.269

Category of Funding Activity:

Health

FOA Purpose

This research is needed to determine: first, best methods for determining a) the population size and vulnerabilities, such as mortality rate and b) the specific needs of these IDPs, especially in urban settings, and second, determine best practices for integrating programs across sectors, such as a) gender-based violence and protection or mental health services, b) access to potable water and improved sanitation and impact on nutrition or water-borne diseases, c) combining mental health and primary healthcare services. The programs should be proven to be effective individually so that the synergy of them is what is investigated.

Key Dates

Publication Date: **To receive notification of any changes to RFA-GH-15-008, 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: **N/A**

Application Due Date: **04/20/2015**

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

Scientific Merit Review: **05/01/2015**

Secondary Review: **06/01/2015**

Estimated Start Date: **09/01/2015**

Expiration Date: **08/31/2020**

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 FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 12 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

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

Executive Summary

- **Purpose.** This research is needed to determine: first, find best methods for determining a) the population size and vulnerabilities, such as mortality rate and b) the specific needs of these IDPs, especially in urban settings, and second, determine best practices for integrating programs across sectors, such as a) gender-based violence and protection or mental health services, b) access to potable water and improved sanitation and impact on nutrition or water-borne diseases, c) combining mental health and primary healthcare services. The programs should be proven to be effective individually so that the synergy of them is what is investigated.
- **Mechanism of Support.** Cooperative agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding for the first year (12 month budget period) will be $500,000 and the estimated total funding for the entire project period will be approximately $2,500,000. There will be up to five awards a year. Awards issued under this FOA are contingent upon availability of funds.
- **Budget and Project Period.** Budget period 09/01/2015 to 08/30/2016; Project period 09-01-2015 to 08-31-2020.
    - **Application Research Strategy Length:** The Research Strategy page limit is 12 pages.
    - **Eligible Institutions/Organizations:** Foreign entities only, specifically located in any country affected by emergencies, conflict or natural disaster, such as countries in Africa or the Middle East, with at least 5 years of proven experience working with displaced populations. The foreign entity in the affected country may be U.S. based. Section III. Eligibility Information
    - **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.** All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 week s.

- PDs/PIs should provide letters of support from the head of their institution as well as curriculum vitas to show previous work in the subject matter/location of work to be conducted.
- **Number of Applications.** Eligible applicant institutions may submit only one application
- **Application Type.** New
- **Application Materials.** See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Sections 301 and 307 (k) (1) and (k) (2) of the Public Health Service Act (42 U.S.C. 242 and 247 b (k) (1) and (k) (2)), as amended.

1. Background and Purpose

By the end of 2013, there were over 33 million internally displaced persons (IDPs, UNHCR. Global trends, 2013); persons uprooted from their homes by conflict and/or natural disaster. An ever increasing number of these persons are living in urban settings, with one estimate being half of all IDPs (Jacobsen K. Feinstein International Center, 2008). Although these persons are similar to non-IDP poor, whether urban, peri-urban or rural, IDPs arrive more impoverished, often traumatized, and lack documentation, support networks, and knowledge of their new surroundings compared with non-IDP poor of the host community. Furthermore, IDPs are not afforded the same protection as refugees by United Nations agencies or international law. As a result, who they are and what their basic needs and vulnerabilities, and protection problems are may be different and greater than the poor of the host population (Davies A. & Jacobsen K. Forced Migration Review, 2010). IDPs are often a hidden population and difficult to identify through the standard methods developed for refugees in closed camp settings.

Furthermore, ability to identify hidden populations, of whom IDPs can be considered one such group, and determine their vulnerabilities, such as mortality rates, and their needs has been broached by partners using many different sampling methods. However, the methods to identify these populations and determine their mortality rates are varied and the methods' validity for emergency purposes has not been documented. There is currently limited evidence to support one method over another, especially in an emergency setting.

Measuring the overall vulnerabilities or impact of programs during acute humanitarian emergencies requires robust mortality data. Prospective mortality data allow observation of trends and therefore the ability to modify programs while single cross-sectional surveys do not. Mortality data in humanitarian emergencies is particularly constrained by opportunity cost, especially if obtained on a

community basis. Few studies have looked at compared the accuracy, feasibility, usefulness and cost-effectiveness of different methods of community-based mortality surveillance (Caleo GM et al. Pop Hlth Metrics 2012). More evidence-based research is needed to determine best methods, determine costs both monitory and in terms of human resources, and establish lessons learned prospectively during an acute emergency affecting internally displaced persons (Working Group for Mortality Estimation in Emergencies. Emerg Themes Epi 2007).

For IDPs, tailored programs are desired. However, the programing and treatment initiatives must avoid the perception of favoring IDPs over the host population. Among existing healthcare services, IDPs are rarely integrated into national healthcare strategy or system. If one considers the potential consequences of epidemic disease in the larger community, IDP and host, it is critical to protect the health security of the whole community. However, often healthcare services for IDPs are seen as competing for limited resources that should be invested in the host community. This perception prevents IDPs from enjoying the same rights to those basic health services as the remaining civilian population (UNHCR, 2006http://www.unhcr.org/4c2355229.pdf).

Core reasons for limited access to basic health services among IDPs are financial and legal (Davies A. & Jacobsen K. Forced Migration Review, 2010). IDPs lack of capacity to pay for healthcare service. These poor financial resources of IDP make it often impossible for them to access existing local healthcare services, which heavily depend on private healthcare service when there is a weak public healthcare system. In addition, public healthcare system, often require proof of health and social insurance that IDPs may lack. By law, many nations take responsibility of protecting health among vulnerable populations. However, lack of documentation and identification make it difficult to access those public healthcare systems. IDPs' specific needs include access to public healthcare, clean water, housing, livelihood, education and legal protection. Therefore, careful evaluation of legal, social and cultural barriers of IDPs should be undertaken in the regional context.

In this context, emergency response aid should facilitate a window of chance for local communities to think or plan differently from the past to allocate their resources with the help from outside. Some issues to consider include impact of internally displacement on the local health system, resilience of the local health system to response to the overlapped health needs of IDPs, improved integration in protection, education and mental health in the community housing IDPS. The importance of evidence on effective programming that tries to integrate across different sectors is ever greater. The evaluation of programs needs to include the consideration of sustainability, including financing; legal authority; and social and cultural barriers, which can be critical to advise health professionals and policy makers to make a salient decision. Guidance can be found in the Framework for program evaluation in public health: A checklist of steps and standards (available at www.wmich.edu/evalctr/checklists/evaluation-checklists). Furthermore, in light of today's limited resources, great needs, and competing interests, it is important to design programing and treatment for IDPs that are not *siloed* but integrated across sectors and populations.

Positive effects have been reported when safe drinking water and improved sanitation and hygiene is integrated into other programs, such as maternal–child health, nutrition, diarrhea and respiratory diseases control, control of other neglected tropical disease, and public health in non-emergency settings (Platt. WASH Advocates, January 23, 2013). USAID has endorsed the integration of WASH into nutrition programming in their Bureau for Global Health five-year project (http://www.washplus.org/sites/default/files/wash_nutrition2013.pdf). However for improved WASH effects on nutritional status, one systematic review found that few studies had provided information on intervention adherence, attrition or cost nor had few used high quality methods or been of sufficient duration (Dangour et al. The Cochrane Library, 2013).

Newborn survival is intricately linked to maternal survival. A newborn is 3-10 times more likely to die within its first two years of life without its mother. CDC's current programmatic approach places emphasis on interventions to enhance the survival of the mother and newborn. However, there is limited data on the effectiveness of neonatal health interventions in humanitarian settings. Humanitarian researchers have called attention to the need to advance neonatal healthcare programming (Spiegel et al. Lancet 2010; Salama et al. Lancet 2004; Moss et al. WHO Bulletin 2006).Additionally, preventing a mother's death can be considered a very effective intervention for the assuring the well-being and survival of a child and is critical for achieving child survival goals. There is a need to adopt a more comprehensive approach to neonatal and child survival by improving pregnancy outcomes and investment in interventions to improve pregnancy outcomes that are likely to improve neonatal and child survival.

Proper hand washing is critical both in the delivery room and the nursery. The rationale for hand washing /hand rubbing is reduction of transient micro flora. Besides maternal-child transmission, environmental organisms in the delivery room and the nursery may place a role in neonatal sepsis cases (Zaidi AKM, *et al*., Ped Infect Dis J Jan 2009); the organisms in the environment of the delivery room and the nursery may be transmitted to the neonates due to breaches in the infection control precautions. A re-emphasis on improving pregnancy outcomes is thus critical to reduce maternal and neonatal mortality and the role hygiene plays needs further investigation.

Therefore research is needed for how can we best integrate specific sectors, improved water, sanitation and hygiene (WASH); food security and nutrition; and different aspects of health action, to increase the individual IDP and public health impact given the resource constraints of today. The programs should be proven to be effective individually so that the synergy of them is what is investigated.

Although ERRB continues to work to address the medical needs of displaced populations, mental health needs often go unaddressed (Prince M, *et al.,*The Lancet 2007). Displaced populations worldwide are at particularly high risk for developing mental health problems. Surveys of displaced populations have demonstrated prevalence of posttraumatic stress disorder symptoms (PTSD) from 5% to almost 40% and of depressive symptoms from 30% to almost 70%. (Mollica RF, *et al.,* The Lancet 2004;Lopes Cardozo B, *et al.,* JAMA, 2004;Lopes Cardozo, *et al.,* JAMA, 2000; Husain F,et al., JAMA 2011; Mollica RF,et al., JAMA. 1993).

The World Health Organization (WHO) Mental Health Gap Action Programme (mhGAP) aims at scaling up services for mental, neurological and substance use disorders; they estimate that as many as 75% of people with those disorders remain under-treated (WHO. Mental Health GAP Action Programme (mhGAP) 2002; WHO. mhGAP 2012, http://www.who.int/mental_health/mhgap/mhGAP_forum_2012.pdf?ua=1). The approach to use primary health care providers to deliver basic mental health services could be used among displaced populations where there is often a lack of mental health providers and services but where basic medical needs are provided. WHO has proposed the mhGAP as part of the humanitarian response, to provide a relatively low-cost sustainable answer to the mental health needs of extremely vulnerable populations. One example is among the 10.8 million Syrians in need of humanitarian assistance, roughly a third of the population, who are displaced by the violent civil conflict (UN, June 2014). Mental health screening instruments for use by primary care providers and training manuals for primary care providers to address mental health issues during humanitarian response have been developed by the International Medical Corps (IMC) (World Health Organization, 2010. http://www.who.int/mental_health/publications/mhGAP_intervention_guide/en/;http://www.youtube.com/playlist?list=PL8EFD1932C0CF4C96&;feature=plcp). Research is needed to evaluate the effectiveness and impact of integration of basic mental health services into

primary health care in displaced populations.

As noted, IDPs suffer from violent conflict and are victims to gender-based violence. However, recent global review of gender-based violence (GBV) prevention and response efforts in humanitarian settings reveals a dearth of evidence-based programs in this arena as well (Asgary, R. et al, International Health, 2013). As part of their mandate to provide guidance on prevention and response to GBV in emergencies, the Gender-based Violence Area of Responsibility (GBV AoR, www.gbvaor.net) has revised and updated the Inter-agency Standing Committee (IASC) Guidelines on GBV Programming in Emergency Settings which will be finalized in early 2015. The overall goal of the Guidelines is to support humanitarian stakeholders across all sectors to fulfill their responsibility to protect all those affected by crises. The rollout of these guidelines provides an opportunity to build capacity and evaluate the effectiveness of integration of GBV efforts across all humanitarian sectors.

Priority areas to consider for research and some of the topics to address (only one priority focus area and research topic per application) could include, but not be limited to:

1. Identify sampling methods for surveys of displaced persons living in urban settings,
    a. Assess current methods and possible future sampling methods of urban displaced persons to determine population size
2. Develop a feasible and useful method to collect prospective mortality data among displaced persons early on in acute emergencies
3. Improve growth and reduce morbidity through integrating WASH and nutrition interventions
    a. Impact of integrating WASH programming on nutritional status of acutely malnourished children in CMAM program
4. Improve health and reduce morbidity through integrating WASH and healthcare activities
    a. Impact on diarrhea or respiratory diseases control with providing WASH measures as a part of primary healthcare delivery
5. Reduce maternal and neo-natal mortality with integrated hygiene interventions
    a. Impact of ensuring hand washing facilities and promoting use of hand disinfectant on maternal and neonatal outcomes
    b. Impact of the Inter-agency Newborn Health Field Package on neonatal mortality and health
6. Reduce morbidity associated with mental health problems among displaced persons
    a. Effectiveness and impact of the integration of basic mental health services into primary health
7. Improve implementation and integration of gender-based violence (GBV) programs in other sectors
    a. Effectiveness and impact of integration of psychological first aid training for health sector personnel as part of capacity building for GBV response
    b. Effectiveness and impact of the integration of the GBV Guidelines into humanitarian sectors

Healthy People 2020 and other National Strategic Priorities

Public Health Impact

Relevant Work

1) List at least 5 countries where you currently work: the area of country-camp, urban, peri-urban; size and characteristics of displaced populations; and length of time in each country by months and years (must have at least 5 years of experience in the field of emergency response).

2) Include what sectors (environmental health, nutrition, and health such as infectious diseases, reproductive health, mental health) this work involves and demonstrate that work by existing letter, agreements, website, etc.

3) Provide letter of intent or other form of communication between government and/or United Nations agency where you are working in listed countries.

2. Approach

Objectives/Outcomes

Objectives/Outcomes – Any one applicant should address integration across or within sectors of WASH, food security/nutrition, or health action.The outcomes are to determine the best practices for integrating programs across sectors picking programs already proven to be effective individually and determining the synergetic effect of integration. An applicant may also address best methods for determining size and vulnerabilities of displaced population(s) or for determining their needs.

Target Population

The population is IDPs in a variety of locations, urban, peri-urban or rural

Collaboration/Partnerships

Given that this is a cooperative agreement, substantial involvement from CDC is expected from both scientific or program staff to assist, guide, coordinate, or participate in project activities as indicated in this FOA under Section VI 2. Additional Policy Requirements/ Cooperative agreement terms and conditions. Additionally, partnership involves collaboration with local governments and humanitarian organizations in the methods to implement scientific measurement of needs and outcomes; operational research related to program implementation, integration, and evaluation. Letters of support from partnership collaborations are requested.

Evaluation/Performance Measurement

Process and outcome evaluation of integrated programs will be needed following guidance found in the Framework for program evaluation in public health: A checklist of steps and standards (available at www.wmich.edu/evalctr/checklists/evaluation-checklists).

Translation Plan

Awardee may participate in conference with CDC project official(s) and research team; and attend in-person or conference call meetings with CDC co-investigators.

• CDC will provide technical assistance in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.

• In collaboration with CDC, awardee may present at national or international meetings and publish research findings in peer-reviewed scientific journals.

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: $2,500,000

The estimated total funding for the first year (12 month budget period) will be $500,000 and the estimated total funding for the entire project period will be approximately $2,500,000. Awards issued under this FOA are contingent on the availability of funds. To include Direct and Indirect Costs

Anticipated Number of Awards: 5

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

Award Ceiling: $500,000 Per Budget Period

Award Floor: $150,000 Per Budget Period

Total Project Period Length: 5 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: Public and State controlled institutions of higher education
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education

Others (see text field entitled "Additional Information on Eligibility" for clarification)

Other:

Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance. Delete when Foreign Organizations are not allowed to apply

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

Foreign Organizations **are** eligible to apply.

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

1. List at least 5 countries where you currently work: the area of country-camp, urban, peri-urban; size and characteristics of displaced populations; and length of time in each country by months and years (must have at least 5 years of experience in the field of emergencies).

2. Include what sectors (environmental health, nutrition, and health such as infectious diseases, reproductive health, mental health) this work involves and demonstrate that work by existing letter, agreements, website, etc.

3. Provide letter of intent or other form of communication between government and/or United Nations agency where you are working in listed countries.

•This agreement builds on work that CDC/CGH/DGHP/ERRB has been developing. Over that time, successful ERRB technical partners with proven experience in their respective fields have been almost exclusively non-governmental organizations and universities with a presence in at least 5 (five) countries. It is important to maintain this consistency, and ensure that the successful recipient has the related capacity and experience to continue the effort.

• Successful recipient must have a demonstrable record and existing staff, both domestically and internationally, trained in public health and science related to environmental health, nutrition, infectious diseases, mental health, and/or reproductive health. CDC/CGH/DGHP/ERRB has worked with numerous organizations in humanitarian emergencies and natural disasters, and considers that only those

non-governmental organizations, universities, colleges or research institutions with a proven track record of at least 5 years on-the-ground experience would be qualified to complete the required tasks.

• Successful recipient must have a significant global presence, allowing it to coordinate with local governments, and non-governmental and international organizations in the implementation of operational research related to program implementation and evaluation, scientific measurement of needs and outcomes for emergency-affected, conflicts and natural disasters, populations.

• The limited duration of this grant requires that a successful vendor begin work immediately upon receipt of the award. CDC/CGH/DGHP/ERRB considers that this can only be accomplished by an established non-governmental organization, university, college, or research institution with experience operating in humanitarian emergencies, conflicts and natural disasters.

• Successful recipient must have an intimate knowledge of the non-governmental and international organizations related to program implementation and evaluation, scientific measurement of needs and outcomes for emergency-affected, conflicts and natural disasters, populations. CDC/CGH/DGHP/ERRB believes that the most experienced potential recipients are those which have established themselves as active participants in the international non-governmental community as providers of support to individuals, families, and communities affected by conflict and natural disasters. This essential connection will provide the successful grant recipient the resources and contacts to implement the program.

4. Justification for Less than Maximum Competition

5. Responsiveness

Applicant should meet criteria in eligibility and should stay within the scope of the FOA.

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

Applicant organizations may submit only one application per priority area.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

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

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

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

3. Letter of Intent

Due Date for Letter of Intent:

N/A

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)
5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

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

9. Inclusion of Children

Other Research Plan Sections

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

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

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 5 PDF files with a maximum of 40 pages for all appendices.

8. Format for Attachments

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

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

9. Submission Dates & Times

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

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from

Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

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

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

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

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

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

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

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

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

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
    a. If the status states "***rejected***," do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA

(pgotim@cdc.gov) explaining why the submission failed.
b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **04/20/2015**

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

10. Intergovernmental Review (E.O. 12372)

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

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

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may 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.
- 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 grantees for currency exchange fluctuations through the issuance of supplemental awards.
- Foreign grantees are subject to audit requirements specified in 45 CFR 74.26(d). A non-Federal audit is required, if during the grantees fiscal year, the grantee 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 grantee either may 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 grantee 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 fiscal Grantee Capability Assessment may 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.
- If research involves human subjects, funds will be restricted until a Federal Wide Assurance (FWA) and Institutional Review Board Approvals (IRB) are in place.
- Projects, if directed by CDC staff and involve the collection of information from 10 or more individuals, and are funded by a grant/cooperative agreement, will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address:

http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

12. Other Submission Requirements and Information

The costs generally allowable in grants to U.S. domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the World Health Organization, HHS/CDC will not pay Indirect Costs (either directly or through sub-award) to organizations located outside the territorial limits of the United States, or to international organizations regardless of their location.

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

Does 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 humanitarian emergencies? 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 emergency-affected population?

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?

Do the investigators have a successful track record in public health research in emergencies? Is there evidence of past collaborations with the proposed research team? Have previous research results provided high quality outputs and contributed to improvements in public health practice and displaced population health?

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?

Does the application challenge and seek to shift current public health practice paradigms or approaches,as far as new methods and practices in emergency situations? Does the project have the potential to increase efficiency or lead to cost savings, especially among integrated sectors?

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? If the project is in the latter stages of development, will the strategy establish scalability? If the FOA requires an evaluation plan, are outputs identified and program evaluation are measures/metric to assess outcomes included? If the FOA requires a translation plan, does the application describe how the results from the research will be disseminated and ultimately used?

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 project utilize critical partnerships or collaborations? Does the project support key stakeholder involvement throughout the research process?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

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

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http://www.cdc.gov/maso/Policy/Policy_women.pdf and http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1) and the policy on the Inclusion of Persons Under 21 in Research (http://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

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 Plans
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/grants/additionalrequirements/index.html#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a

detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

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

FOA.

Specific requirements that apply to this FOA are the following:

AR-1: Human Subjects Requirements

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

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-25: Release and Sharing of Data

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

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

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

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

http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_memo.html)

Federal Funding Accountability and Transparency Act of 2006

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

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

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

  - http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

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

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

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

4. Cooperative Agreement Terms and Conditions of Award

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

The administrative and funding instrument used for this program will be the cooperative agreement,

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

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

- 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.
- Providing the necessary personnel and supplies to implement components and analyze the results.
- Collaborating with local senior researchers, 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 data-collection instruments, specimen-collection protocols, and data-management procedures.
- Awardees will obtain IRB approval for all the collaborators and work with CDC scientists to refine protocols to improve the study and other proposal components based on reviewer's comments in the summary statement.
- Awardee will identify, recruit, obtain informed consent form, and enroll an adequate number of study participants, as determined by the study protocols and the program requirements
- Follow study participants as determined by the study protocols.
- Establish procedures to maintain the rights and confidentiality of all study participants.
- Agree to share data and specimens with CDC scientists, as well as appropriate international partners, such as the World Health Organization.

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

- 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.
- 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.
- Provide technical assistance to the recipient by linking them with other national and international agencies that might provide additional technical or material assistance.
- Collaborate with the affiliated institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
- Provide assistance as requested 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.
- Projects, if directed by CDC staff and involve the collection of information from 10 or more individuals, and are funded by a grant/cooperative agreement, will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act

- 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.
- Monitor the cooperative agreement.
- If appropriate, Epidemic Intelligence Officer(s) and CDC staff with accompany the awardee with field investigation.
- Provide technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the awardee. All such data collections--where CDC staff will be or are approving, directing, conducting, managing, or owning data--must undergo OMB project determinations by CDC and may require OMB PRA clearance prior to the start of the project.

Areas of Joint Responsibility include:

None; all responsibilities are divided between awardees and CDC staff as described above.

5. Reporting

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

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

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal

government.

2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm) http:// grants.nih.gov/grants/ funding/2590/2590.htm: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

  b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include*:

  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected

reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:
    - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
    - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

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

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

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

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

FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm.

For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

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

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts
Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)
Susan T. Cookson

Emergency Response & Recovery Branch

Center for Global Health (CGH)

Telephone: (770) 488-0692 Email: sgc0@cdc.gov

Peer Review Contact(s)

Hylan Shoob

CGH Science Office

MS D-69, 1600, Clifton Road

Atlanta, GA 30033

Telephone: 404-639-4796

E-mail: hshoob@cdc.gov

Financial/Grants Management Contact(s)
Steward Nichols

Centers for Disease Control and Prevention

Procurement and Grants Office (PGO)

Telephone: (770) 488-2788

Email: shn8@cdc.gov

Section VIII. Other Information

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

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

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