Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases

Vector-Borne Disease Regional Centers of Excellence
RFA-CK-22-005
01/18/2022

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center for Emerging and Zoonotic Infectious Diseases

Notice of Funding Opportunity (NOFO) Title

Vector-Borne Disease Regional Centers of Excellence

Activity Code

U01 - Research Project - Cooperative Agreement

Notice of Funding Opportunity Type

Reissue of

Agency Notice of Funding Opportunity Number

RFA-CK-22-005

Assistance Listings Number(s)

93.084

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support research to improve national capacity to address the growing problem of vector-borne diseases (VBDs) via continued support for regional Centers of Excellence (COEs) for Vector-Borne Diseases. The primary focus of each individual COE should be on the regionally most important arthropod vectors, particularly ticks and mosquitoes, and their associated human disease agents. Applications should include a strong focus on ticks and tickborne disease agents, if relevant to the applicant's geographic region. Inclusion of work on mosquitoes and mosquito-borne disease agents is also

strongly encouraged. The specific goals for COEs should be to: (1) conduct applied research on approaches to prevent vector bites or suppress regionally important arthropod vectors and their associated human disease agents in the environment; (2) increase public health workforce knowledge of medical entomology through training and engagement of undergraduate and graduate students, as well as post-doctoral staff, in research activities; and (3) strengthen linkages and collaborative relationships between the academic community, state, territorial, tribal or local public health organizations, and other relevant stakeholders, in the context of enhancing activities related to vector-bite prevention and suppression of vectors and their associated human pathogens.

Key Dates

Publication Date:

To receive notification of any changes to RFA-CK-22-005, 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:
12/17/2021
12-17-21

Application Due Date:
01/18/2022
01-18-22

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

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

Scientific Merit Review:
03/17/2022

Secondary Review:

04/19/2022

Estimated Start Date:
07/01/2022

Expiration Date:
01/19/2022

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.

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

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

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

Executive Summary

- **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to support research to improve our national capacity to address the growing problem of vector-borne diseases (VBDs) via continued support for regional Centers of Excellence (COEs) for Vector-Borne Diseases. The primary focus of each individual COE should be on the regionally most important arthropod vectors, particularly ticks and mosquitoes, and their associated human disease agents. Applications should include a strong focus on ticks and tickborne disease agents, if relevant to the applicant’s geographic region. Inclusion of work on mosquitoes and mosquito-borne disease agents is also strongly encouraged. The specific goals for COEs should be to: (1) conduct applied research on approaches to prevent vector bites or suppress regionally important arthropod vectors and their associated human disease agents in the environment; (2) increase public health workforce knowledge of medical entomology through training and engagement of undergraduate and graduate students, as well as post-doctoral staff, in research activities; and (3) strengthen linkages and collaborative relationships between the academic community, state, territorial, tribal or local public health organizations, and other relevant stakeholders, in the context of enhancing activities related to vector-bite prevention and suppression of vectors and their associated human pathogens.
- **Mechanism of Support:** U01 Research Project - Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is $100,000,000. The estimated number of awards is ten (10). 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 cost of the applications received.

- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $20,000,000 with individual awards ranging from $1,500,000 to $2,000,000 for the first year. The estimated total funding (direct and indirect) for the entire project period is $100,000,000. The project period is anticipated to run from 07/01/2022 to 06/30/2027.
- **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. 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 PD/PI for each application.
- **Number of Applications.** Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. **Please note that Form F is to be used when completing the application package.**

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Section 301(a) [42 U.S.C 241(a)] and Section 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended.

1. Background and Purpose

Vector-borne diseases pose a large and growing public health problem in the U.S. During the 12-year period from 2004 to 2016, a total of 642,602 vector-borne disease cases were reported to the National Notifiable Diseases Surveillance System. Diseases affecting large portions of the 48 contiguous states include tick-borne diseases such as Lyme disease (>400,000 cases from 2004-2016), anaplasmosis/ehrlichiosis (>39,000 cases from 2004-2016), spotted fever rickettsiosis (>37,000 cases from 2004-2016), and babesiosis (>9,000 cases during the reportable six-year period from 2011-2016) and mosquito-borne diseases such as West Nile virus disease (>31,000 cases from 2004-2016). Moreover, the true number of annual Lyme disease cases is estimated to be 10-fold higher than the reported cases. Additional notable diseases with limited geographical reach within the 48 contiguous states, but nevertheless of great importance as they cause large outbreaks in U.S. territories (for example, Puerto Rico), include mosquito-borne

dengue (>46,000 cases from 2004-2016), Zika virus disease (>41,000 cases in 2016) and chikungunya (>9,000 cases during the three-year period from 2014-2016). Additionally, changing climatic conditions are likely to alter the geographic range and seasonal activity of vectors, potentially modifying populations at risk for vector-borne diseases. Without the development and deployment of safe and effective prevention strategies, including vector suppression and bite-prevention tools, the trends of increasing incidence and expanding geographic range of vector-borne diseases is expected to continue.

Although other tick vectors can be of local importance, the overwhelming number of tick-associated disease cases, or other medical conditions related to tick bites, in the 48 contiguous states are associated with bites by *Ixodes* spp. ticks (*Ixodes scapularis* and to some extent also *Ixodes pacificus*) or *Amblyomma* spp. ticks (primarily *Amblyomma americanum* but also *Amblyomma maculatum*). Similarly, although other mosquito vectors can be of local importance, the overwhelming number of mosquito-associated disease cases arise from *Culex* spp. mosquitoes (primarily *Culex pipiens*, *Culex quinquefasciatus*, and *Culex tarsalis*) or *Aedes* spp. mosquitoes (*Aedes aegypti*, *A. triseriatus* and to some extent also *Aedes albopictus*).

The burden of tick-borne disease has been relatively consistent each year, but there has been an increasing trend over time from <30,000 reported cases per year during 2004-2006 to >40,000 cases each year from 2011-2016. The burden of mosquito-borne, arboviral diseases is more variable across years, as outbreak years for individual arboviral diseases are interspersed with years of lower virus activity. Introduction of new human-pathogenic mosquito-borne viruses to the Americas remains a concern as they are likely to cause major outbreaks where human-biting vector mosquitoes are present. Overall, in the 48 contiguous states, the occurrence of tick-borne diseases is predictable both in space and time (across years and within pathogen transmission seasons) whereas outbreaks of mosquito-borne, arboviral diseases are more difficult to predict both in space and time (e.g., West Nile virus disease) or over time where there is a history of previous outbreaks (e.g., dengue, chikungunya, and Zika virus disease). Therefore, the control of tick versus mosquito-borne disease agents presents the public health community with different sets of challenges.

Previous funding for regional COEs for vector-borne diseases was driven, in large part, by shortcomings in public health entomology capacity in the U.S. as revealed by the Zika virus disease emergency response. Shortcomings included gaps in our knowledge of the distribution in the 48 contiguous states of key mosquito vectors (*Aedes aegypti* and *Aedes albopictus*) and a general shortage of adequately trained public health entomologists at local, state, and federal levels. Additionally, there was a need for improved mosquito control program capacity across the nation as shown through the 2017 National Associated of County and City Health Officials (NACCHO) assessment on mosquito control capabilities in the U.S. The previously funded COEs for vector-borne diseases responded with robust activity across the three themes: 1) training of public health entomologists, 2) building communities of practice, and 3) conducting applied research. To fill some of the most urgent knowledge gaps, the applied research component of the initial COEs for vector-borne disease focused strongly on topics relating to where and when humans are at risk for vectors and their associated disease agents, including: better defining the geographical distributions of key endemic and invasive vector species and their associated pathogens via field collections/pathogen detection and modeling; conducting vector competence studies with emerging pathogens; elucidating drivers for vector population growth and risk of exposure to vector-borne human pathogens; improving methodology for vector collection; and developing new technology for communication of information about

vectors to the public. The substantial progress made in these areas, together with strengthening of funding for vector surveillance via CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) program, motivates a shift in the focus of applied research for this cooperative agreement to vector bite prevention and vector suppression rather than vector surveillance and modeling.

To continue to improve national capacity to address the growing problem of vector-borne diseases and respond to changing vector-borne disease dynamics due to climate change and other environmental and sociological drivers, this NOFO includes the same three major themes as the earlier NOFO but with a greater emphasis on applied research as a means of answering pressing scientific questions and training of public health entomologists. In addition, the applied research should focus more narrowly on approaches to prevent vector bites and/or suppress the populations of regionally important arthropod vectors and their associated human disease agents in the environment. This aspect of the applied research addresses the main roadblocks to stemming the rising tide of vector-borne diseases: 1) a limited evidence base for optimal schemes to suppress tick and mosquito populations in the environment, including approaches to minimize the environmental impact of pesticides and better manage pesticide resistance; and 2) a weak empirical evidence base for either personal protective measures or environmentally based control methods to reduce human tick bites or human infection with tick- or mosquito-borne pathogens. Additionally, there is an urgent need to evaluate the effectiveness of existing vector bite prevention and vector suppression approaches, as well as to continue to pursue novel and innovative control technologies.

To ensure that COE activities align with the goals of this NOFO, project progress will be assessed at least annually. Training activities should focus on undergraduate and graduate student (M.S. and Ph.D.) as well as postdoctoral training through involvement in the described applied research activities. Additionally, modest outward focused training programs, targeting vector-control professionals, may be included. Communities of Practice should be developed and maintained to ensure that all stakeholders and skill sets needed to address the applied research focus are represented. Public outreach activities should be coordinated with CDC technical/communication staff to ensure that COE and CDC messaging is not contradictory.

Healthy People 2030 and other National Strategic Priorities

This NOFO aims to: a) support the expansion of the pool of trained and competent entomologists in the public health workforce and b) provide public health personnel the evidence base needed to take effective action to reduce morbidity and mortality from vector-borne diseases. Additionally, objectives in this NOFO are consistent with A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans (https://www.cdc.gov/ncezid/dvbd/framework.html). Applicants should review and become familiar with the Framework before applying.

Public Health Impact

Key outcomes may include: a) improved methodology to suppress tick and mosquito vectors in the environment under a range of different climatic conditions representing current and future projected climate scenarios with a focus on demonstrating efficacy in the current core distribution of VBDs of interest; b) evaluation of personal protective measures, or environmentally based control methods, to reduce vector bites in humans or reduce human infection with tick or mosquito-borne pathogens; c) a stronger evidence base to support data-driven recommendations for tick or mosquito-borne disease control and prevention, focusing on

environmental interventions that are effective as well as affordable and acceptable to a substantial sector of the U.S. population; d) increased number of trained and competent public health entomologists, particularly those who can play a future leadership role in VBD prevention research; and e) improved communication and collaboration among academic institutions, state/local public health agencies and other stakeholders to better harness the academic research expertise in projects of direct relevance to the mission of state/local public health agencies and mosquito/vector management programs.

Health Equity

The program supports efforts to improve the health of populations disproportionately affected by infectious diseases by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity.

A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in infectious diseases are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after health disparities are eliminated.

Programs should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by infectious diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

Relevant Work

1. Beard CB, Visser SN, Petersen LR. The need for a national strategy to address vector-borne disease threats in the United States. *J Med Entomol*. 2019; 56:1199-203.
2. Beard, CB, Eisen RJ, Barker CM, Garofalo JM, Hahn M, Hayden M., Monaghan AJ, Ogden NH, Schramm PJ, 2016: Ch. 5: Vector borne Diseases. The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment. U.S. Global

Change Research Program, Washington, DC, 129–156. http://dx.doi.org/10.7930/J0765C7V
3. Eisen L. Stemming the rising tide of human-biting ticks and tickborne diseases, United States. *Emerg. Infect. Dis*. 2020; 26:641-7.
4. Eisen L. Control of ixodid ticks and prevention of tick-borne diseases in the United States: The prospect of a new Lyme disease vaccine and the continuing problem with tick exposure on residential properties. *Ticks Tick Borne Dis*. 2021; 12:101649.
5. Eisen L., Stafford III KC. Barriers to effective tick management and tick-bite prevention in the United States (Acari: Ixodidae). *J. Med. Entomol*. 2020; 57: doi: 10.1093/jme/tjaa079.
6. Eisen RJ, Eisen L. The blacklegged tick, *Ixodes scapularis*: An increasing public health concern. *Trends Parasitol*. 2018; 34:295-309.
7. Eisen RJ, Kugeler KJ, Eisen L, Beard CB, Paddock CD. Tick-borne zoonoses in the United States: Persistent and emerging threats to human health. *ILAR J*. 2017; 58:319-35.
8. Hinckley AF, Connally NP, Meek JI, Johnson BJ, Kemperman MM, Feldman KA, *et al*. Lyme disease testing by large commercial laboratories in the United States. *Clin Infect Dis*. 2014; 59:676–81.
9. Hinckley AF, Meek JI, Ray JAE, Niesobecki SA, Connally NP, Feldman KA, *et al*. Effectiveness of residential acaricides to prevent Lyme and other tick-borne diseases in humans. *J Infect Dis*. 2016; 214:182-8.
10. Kugeler KJ, Schwartz AM, Delorey MJ, Mead PS, Hinckley AF. Estimating the frequency of Lyme disease diagnoses, United States, 2010-2018. *Emerg. Infect. Dis*. 2021;27: doi: 10.3201/eid2702.202731.
11. Molaei G, Little E, Williams SC, Stafford KC. Bracing for the worst – Range expansion of the lone star tick in the northeastern United States. *N Engl J Med*. 2019; 381:23.
12. NACCHO. 2017. Mosquito Control Capabilities in the U.S. Washington, DC: National Association of County and City Health Officials. https://www.naccho.org/uploads/downloadable-resources/Mosquito-control-in-the-U.S.-Report.pdf.
13. Nasci R, Mutebi J-P. Reducing West Nile virus risk through vector management. *J Med Entomol*. 2019; 56:1516-21.
14. Petersen LR, Beard CB, Visser SN. Combatting the increasing threat of vector-borne disease in the United States with a national vector-borne disease prevention and control system. *Am J Trop Med Hyg*. 2019; 100:242-5.
15. Rochlin I, Faraji A, Healy K, Andreadis T. West Nile virus vectors in North America. *J Med Entomol*. 2019; 56:1475-90.
16. Rosenberg R, Lindsey NP, Fischer M, Gregory CJ, Hinckley AF, Mead PS, *et al*. Vital signs: Trends in reported vectorborne disease cases — United States and Territories, 2004-2016. *Morb Mort Wkly Rep*. 2018; 67:496-501.

2. Approach

The proposed approach is expected to involve a multi-disciplinary team of scientists and public health practitioners, led by a Principal Investigator with a strong, proven background in vector biology and control, and vector-borne disease prevention. The approach should be developed in collaboration with a diverse group of experts from academia, state/local public health agencies, and vector management programs. The project should address all three of the objectives

described below and include applied research focused on vector-bite prevention or vector population suppression, training, and communities of practice.

Objectives/Outcomes

Project objectives should be threefold: 1) conduct applied research on approaches to prevent vector bites or suppress the populations of regionally important arthropod vectors and their associated human disease agents in the environment; 2) train a new generation of public health entomologists to serve as subject matter experts for arthropod pathogen vectors at state/local levels by involving undergraduate/graduate students and postdoctoral fellows in applied research; and 3) strengthen linkages and collaborative relationships between the academic community and state/territorial/tribal/local public health organizations, vector management programs and other potentially relevant stakeholder groups, as needed, to develop, evaluate and implement vector and vector-borne pathogen suppression strategies. In short, the primary focus should be on applied research with training and communities of practice elements designed to enhance applied research outcomes.

The proposed applied research projects should be guided by public health needs and are expected to be scientifically sound, statistically robust, and directly relevant to the mission of territory, state, local or tribal public health agencies, publicly funded mosquito/vector management programs, and private pest control companies or homeowners involved in control of vectors, particularly ticks and mosquitoes. The emphasis of the applied research activities should be on intervention studies aiming to evaluate existing or emerging approaches to the prevention of vector bites or suppression of vector populations of regional importance. Applications should include a strong focus on ticks and tick-borne pathogens. Intervention evaluations are expected to minimally include entomological outcome measures (abundance of host-seeking tick vectors; prevalence of infection in the tick vectors; abundance of infected host-seeking tick vectors; tick infestation of key reproductive or pathogen reservoir hosts; abundance of mosquito vectors; prevalence of infection in the mosquito vectors; abundance of infected mosquito vectors; and abundance of mosquito immatures) and, ideally, when applicable and feasible, also human-related outcome measures (e.g., human-tick encounters and bites; evidence of human tick-borne illness; evidence of human exposure to mosquito-borne pathogens; and evidence of human mosquito-borne illness).

Please note: In this cooperative agreement, CDC does not plan to fund research pertaining to the development of diagnostics for vector-borne disease pathogens in humans or vaccine research other than the specific vaccine initiative detailed below.

Testing of interventions aimed at preventing vector bites or suppressing vector populations across varying climate/ecologic settings to demonstrate robustness of findings is encouraged. Climate-related activities should focus on empirical, rather than theoretical applications aimed at suppressing vector populations or preventing vector bites. Studies to model the impact of climate change on vectors are not encouraged unless they relate directly to specific vector control methodologies.

A. Proposed research should focus on the following:

Ticks

- Laboratory or field evaluations of emerging technologies to suppress host-seeking ticks or disrupt pathogen transmission cycles (entomological outcome measures).
- Field evaluations of commercially available technologies/products for tick/pathogen management in approaches that include either single or integrated methodologies (minimally with entomological outcome measures, ideally also with human-related outcome measures such as human-tick encounters).
- Laboratory or field evaluations of personal protective measures to prevent human-tick encounters resulting in tick bites.
- Impact of landscaping and vegetation management on residential properties or in high-use public areas on the density of host-seeking ticks.
- Field studies aimed at optimizing application of tick control products to provide recommendations for pest control firms and homeowners regarding how to optimize tick suppression depending on type of product used, application method, timing of applications and vegetation structure in the treated area.
- Laboratory or field studies to test novel methods for control of brown dog tick (*Rhipicephalus sanguineus*) populations on dogs.
- Development of vaccines that protect dogs from infection with *Rickettsia rickettsii.*
- Development or early-stage evaluation of novel deer-targeted tick control strategies, including modifications to existing technologies to increase their effectiveness and acceptability.
- Assessments of the potential for incorporating tick management into existing mosquito management programs.
- Investigations on the knowledge, attitudes, and behaviors regarding tick control methodologies.
- Evaluation of the impact of existing public education programs on human behaviors to prevent tick bites.

Fleas

- Evaluation of the prevalence of flea-borne pathogens (*Rickettsia typhi, Rickettsia felis, Bartonella henselae*) in flea populations from diverse geographic areas.

Mosquitoes

- Field evaluations of emerging technologies to suppress mosquito immatures or adults (entomological outcome measures).
- Field evaluations of mosquito management approaches based on commercially available methods and products (minimally with entomological outcome measures, ideally also with human-related outcome measures).
- Evaluations of the effectiveness of operational control activities targeting mosquito immatures, adults, or multiple life stages (entomological outcome measures).
- Field studies on the impact of insecticide resistance on operational mosquito control activities.

- Evaluation of the impact of existing public education programs on human behaviors to prevent mosquito bites and reduce larval habitat.

Applicants are encouraged to include a particular focus on addressing the mosquito research objectives above on dengue and arbovirus transmission and mosquito control in U.S. insular areas including Caribbean territories (e.g., Puerto Rico, U.S. Virgin Islands) and territories in the Pacific (e.g., Guam, Northern Mariana Islands, American Samoa).

B. The aim of the training component is to build the next generation of public health entomologists qualified to lead university-based research programs or work professionally in medical entomology in public or private institutions. The training components should be multi-level, with the goal of building the next generation of public health entomologists and increasing medical entomology training in university-based educational programs available to undergraduate and graduate students as well as public health professionals already in the workforce. Specific training activities are expected to include the following:

- Train undergraduates, graduate students, and post-doctoral fellows to develop a larger workforce cadre of public health professionals focused on entomology and the prevention and control of vector-borne diseases. University-based education could include certificate programs and inclusion of vector-borne disease control curricula in non-entomology degree programs (e.g., medical, veterinary, nursing, or MPH programs).
- Provide specialized training to existing staff from state/local health departments and territorial, tribal, and municipal institutions in vector identification, vector/pathogen surveillance methods, vector/pathogen control approaches, pesticide resistance monitoring, or public outreach. Examples of accessible trainings for professionals could include in-person workshops, bootcamps, online training and curricula that can be made widely available. An assessment of currently available trainings to identify gaps, avoid redundancy of existing topics and consider collaborations with other institutions is encouraged. Additionally, particular focus on incorporating professional training into university-based research programs is encouraged.
- With special reference to ticks, provide training for vector-control professionals in tick biology and host-seeking behavior to ensure that broadcast applications of acaricides or biological control agents have maximum potential to reach and kill the ticks present in a treated area.

C. The community of practice objective should focus on building effective collaborative relationships that further the goals of identifying safe, effective, and acceptable vector-control strategies and should include the following:

- Establish a community of practice that includes academic institutions, territorial/state/local public health agencies, publicly funded mosquito- or vector-management programs and other relevant stakeholders in combinations that best serve the applied research goals outlined in the COE application.
- Engage with professional vector-control organizations and private pest-control firms involved in vector control to ensure that the applied research projects account for realistic intervention schemes.
- Leverage the collective knowledge of the community of practice to develop and implement the applied research and training components of the overall project.

- Collaborate with partners at the territorial/state/local public health agencies, and publicly funded mosquito- or vector-management programs on discrete projects or programs to address the growing issue of VBDs in the region.
- Applicants are encouraged to consider U.S. non-CONUS locations (e.g., Caribbean, and Pacific island U.S. territories) for inclusion in their communities of practice.

At the end of the project period, there should be evidence of the successful completion of all project objectives and milestones. Evidence for success should include accomplishments such as: a) implementation of projects that address CDC priorities and the National Framework for Vector-borne Diseases; b) published results of research studies with academia; c) engagement of graduate students and postdocs in applied research, including contributions significant enough to justify authorship on resulting publications; and d) evidence of increased use of best practices for vector control by agencies conducting control measures.

Target Population

The target population is all residents of the U.S. and U.S. territories affected by vector-borne diseases. This includes individuals of all races, ethnicities, gender identities, sexual orientations, geographic locations, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions who live in areas that are at risk for contracting an illness that is caused by an agent transmitted by mosquitoes, ticks, fleas, or other arthropod disease vectors. This cooperative agreement includes program activities that could serve populations at disproportionate risk of vector-borne infectious disease and/or adverse outcomes. Where applicable, applications should be inclusive of populations that may be directly impacted or have increased risk for various vector-borne infectious diseases including, but not limited to: a) rural, minority and native populations; b) people living with disabilities; c) justice-involved populations; d) non-English speaking populations; e) lesbian, gay, bisexual, and transgender (LGBT) populations; f) people with limited health literacy; g) immunocompromised persons; and/or h) other populations with increased risk.

Collaboration/Partnerships

The multi-disciplinary research team should be led by a Principal Investigator with significant experience in vector biology and control, and vector-borne disease prevention. The application should be developed in collaboration with a diverse group of experts from academic institutions and public health agencies to ensure that the project is scientifically sound, statistically robust, and directly relevant to the mission of: a) state/local, territorial, and tribal public health agencies; b) publicly funded mosquito/vector management programs; and c) private pest-control firms involved in vector control. Letters of support should be included from key partners to demonstrate willingness and commitment to work together as a team to accomplish the project objectives. It is expected that a project of this magnitude will involve multiple academic institutions working together with multiple public health agencies. Applications should clearly describe how investigators will collaborate with other programs and organizations.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a five (5)-year research project period. The application should describe establishing specific, measurable, achievable, realistic, and time-phased (SMART) project objectives for each activity in the project plan and describe the development and implementation of project performance measures that are based on specific programmatic objectives. Additionally, the applications should propose specific

milestones and deliverables related to the objectives of the work plan. These milestones and deliverables will be used in part to assess COE progress and performance.

Translation Plan
Dissemination of project outcomes is expected to occur via: 1) publication of research results in peer-reviewed scientific journals; 2) presentation of research results at scientific conferences and meetings of professional vector-control organizations; 3) presentation of project information and outcomes via a publicly accessible project website; and 4) inclusion of key findings on the webpages of CDC and territory/state/local public health agencies or revised CDC guidance documents or handbooks.

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (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:
$100,000,000
Year 1: $2,000,000 per award
Year 2: $2,000,000 per award
Year 3: $2,000,000 per award
Year 4: $2,000,000 per award
Year 5: $2,000,000 per award

Anticipated Number of Awards:
10
Estimated total funding available for the first year (first 12 months), including direct and indirect costs, for all awards: $20,000,000
Estimated total funding available for entire project period, including direct and indirect costs, for all awards: $100,000,000

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

Award Ceiling:
$2,000,000
Per Budget Period

Award Floor:
$1,500,000
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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

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

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

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

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

3. Additional Information on Eligibility

- The following types of Higher Education Institutions are always encouraged to apply for CDC support as Non-Profit Public or Non-profit Private Institutions of Higher Education:
    - Hispanic-serving Institutions
    - Historically Black Colleges and Universities (HBCUs)
    - Tribally Controlled Colleges and Universities (TCCUs)
    - Alaska Native and Native Hawaiian Serving Institutions

- Nonprofits (Other than Institutions of Higher Education)
- Private non-profit institutions of higher education
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession
- Faith-based or Community-based Organizations
- Regional Organizations
- Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via https://www.grants.gov
- Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://ecfr.io or https://www.nsf.gov/statistics/ffrdclist/

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

N/A

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.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- 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 Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and

Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS.

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 SAM.gov and the SAM.gov Knowledge Base.

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 NOFO 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.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

*****For this NOFO, please use the form and instructions for SF424 (R&R) Form F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.**

3. Letter of Intent

Due Date for Letter Of Intent 12/17/2021

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

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

Name of the Applicant
Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity announcement

The letter of intent should be sent to:

Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

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

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

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and

- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

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

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

*****For this NOFO, please use the form and instructions for SF424 (R&R) FORMS-F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.**

*****Letters of Support from partners or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".**

*****Please include all of the eight (8) mandatory forms listed below in the application using the forms and instructions for SF424(R&R) Form F:**
Mandatory

1. **SF424(R&R);**
2. **PHS 398 Cover Page Supplement;**
3. **Research and Related Other Project Information;**
4. **Project/Performance Site Location(s);**
5. **Research and Related Senior/Key Person Profile (Expanded);**
6. **Research and Related Budget;**
7. **PHS 398 Research Plan;**
8. **PHS Human Subjects and Clinical Trials Information.**

If multiple collaborating institutions will be involved, please include in this section of the application your single IRB (sIRB) Plan:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.

- Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed sIRB and that any institutions or sites added after award will rely on the sIRB.

- Briefly describe how communication between institutions and the sIRB will be handled.
- Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

Please include the one (1) optional form listed below, if applicable, in the application package:
Optional

1. **R&R Subaward Budget Attachment(s) Form 5 YR 30 ATT.**

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 publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PLEASE NOTE: If applications go beyond the page limit designated for a given section, excess pages will be removed from the application prior to peer review and may negatively affect the application's scoring.

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 15 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 10 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 **and must use FORMS-F application packages for due dates on or before January 24, 2022.**

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

*****For this NOFO, please use the form and instructions for SF424 (R&R) FORMS-F. Applicants must use FORMS-F application packages for due dates on or before January 24, 2022.**

9. Submission Dates & Times

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

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

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

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

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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov

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

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

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 01/18/2022

01/18/2022
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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 and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 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.

Public Health Data:

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.

Data Management Plan:

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/additional-requirements/ar-25.html

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

1. Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously funded research under other awards (no scientific, budgetary or percent effort overlap allowed).

2. **Please note:** Certain grants or recipients are not eligible for expanded authorities. In addition, one or more expanded authority may be overridden by a special term or condition of the award. The Notice of Award (NoA) will indicate the applicability of expanded authorities by reference to the HHS Grants Policy Statement or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are, or are not, permitted to use expanded authorities.

3. Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included in this NOFO. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on sIRB Plan content.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

4. Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.

5. Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

6. 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 may result in suspension, limitation, or termination of US Government (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.

7. Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this NOFO (https://www.cdc.gov/grants/additionalrequirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

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

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding

source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Please note the new requirement for a **Risk Assessment Questionnaire** (described above) that should be uploaded as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application.

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 Senior/Key Personnel (including any Program Directors/Principal Investigators (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.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

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.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS.

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

See more resources to avoid common errors and submitting, tracking, and viewing applications:

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

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

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?

- Will the work be influential in that it will change public health practice?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk for vector-borne disease?

- Does the project focus on the most important arthropod vectors and vector-borne diseases in the region of study, and are the choices of vectors and diseases to focus upon well justified?
- Is the proposed work likely to advance knowledge to recommend acceptable means of controlling vector-borne diseases through personal protection or environmental interventions?
- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, will scientific knowledge, technical capability, and/or public health practice (vector control) be improved?
- Will successful completion of the aims change the concepts, methods, technologies, and interventions that drive this field?
- Will the work be influential in that it will change public health/vector-borne disease control practices?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk for *Ixodes scapularis*-borne diseases?
- Does the project focus on the most promising vector control methodologies, and is the rationale for testing the selected strategies well-supported in the peer-reviewed literature?
- Is the proposed work likely to advance knowledge to recommend acceptable, efficacious and reproducible protocols of controlling *Ixodes scapularis* through environmental interventions?

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 research on arthropod vectors and vector-borne diseases?
- Do the investigators have evidence of peer-reviewed publications and research award support?
- Is there evidence through letters of support or documented successful past collaborations with territory, state, local or territorial public health agencies indicating that the investigators will be successful in building a strong community of practice spanning academia and public health practitioners?
- Have previous research results provided high quality outputs and contributed to improvements in the control of arthropod vectors and prevention and control of vector-borne diseases?
- Does the PI have the leadership ability, scientific stature, and commitment of time to adequately manage a COE?
- Are the qualifications of the PI and faculty in delivering academic and/or short course training in the proposed field adequate?

- For undergraduate, graduate, and post-doctoral training programs, are the accomplishments of the teaching staff and mentors as research investigators in the control of arthropod vectors and in the prevention and control of vector-borne diseases adequate?

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 have the potential to change and improve current public health practice approaches for control of arthropod vectors and prevention and control of vector-borne diseases, including in areas anticipated to be affected by climate change?
- Is the proposed research innovative and yet offer strong potential for concrete applications of interest and value for public health?
- Does the academic program involve new and innovative approaches to training and education relevant to the vector-borne disease prevention and control field?
- Is there evidence of innovation in the plan to develop and sustain a broad and vigorous community of practice working collaboratively across the region of study to reduce human vector bites and vector-borne disease?

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?

- Do the proposed COE activities target the most important arthropod vectors and vector-borne diseases in the geographic region in which the center resides?
- Are the appropriate key stakeholders involved in the applied research projects and training activities being proposed?
- Are there adequate connections among the proposed applied research, training, and community of practice project components to build a synergistic overall program?
- Is the proposed applied research strongly focused on projects aiming to evaluate approaches to prevent vector bites or suppress regionally important arthropod vectors?
- Does the application address issues of feasibility to indicate that tested interventions likely will be acceptable and affordable for use in vector-control programs or by homeowners?

- Are the proposed applied research projects directly relevant to the mission of state/local public health agencies, publicly funded mosquito/vector management programs, and private pest-control companies or homeowners involved in tick or mosquito control?
- Does the application adequately describe how the results from the applied research will be disseminated and ultimately used by vector-control stakeholders?
- Is the proposed training consistent with a high-quality program?
- Are there appropriate administrative arrangements and facilities to stimulate collaboration among constituent projects and personnel?
- Does the testing of interventions include areas across a climate/ecologic gradient to demonstrate robustness 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 application include a letter of support or collaboration from at least two territory, tribal, local, or state health agencies?
- Does the application include plans to involve local public health agencies or publicly funded mosquito- or vector-management programs in the project?
- Does the application focus on a geographic area identified as being at high risk for endemic or emerging vector-borne diseases?
- Will the project benefit from unique features of the scientific environment or collaborative arrangements?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Is the necessary infrastructure present to support a robust undergraduate, graduate and post-doctoral training and research program in the control of arthropod vectors and prevention and control of vector-borne diseases?
- Does the application indicate that the applicant institution and collaborative institutions have or will have established infrastructure in place, including physical facilities, support staff, fiscal and administrative management personnel, information management and communication systems, and computer equipment and technical support?

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of

protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

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

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

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

N/A

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

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

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

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

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

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

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

funding restrictions may be imposed pending submission and evaluation.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

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

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

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

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

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

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

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

4. Review and Selection Process

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

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

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications

will receive a second level of review. The following will be considered in making funding recommendations:

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

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 with 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 45 CFR Part 75, subpart F, 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).

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS.

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
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-15: Proof of Non-profit Status
AR-16: Security Clearance Requirement
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: 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 – Research Definition
AR 32 – Appropriations Act, General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Accessibility Provisions and Non-Discrimination Requirements
AR-36: Certificates of Confidentiality
AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020

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: https://www.cdc.gov/grants/additional-requirements/

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-

obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 applies 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 grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

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

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk

mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

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

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

Data Management Plan(s)

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

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

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

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

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR 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 awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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 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.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant-supported 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 Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- 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.
- Obtaining and maintaining required approvals and permits for laboratory or field research activities involving vertebrate animals (including institutional number and IACUC approval). Sharing approved animal protocols with CDC to allow Technical Advisors to complete CDC internal animal use project determinations

- Working with CDC Technical Advisors to obtain CDC Institutional Review Board approvals and Office of Management and Budget/Paperwork Reduction Act approvals, as needed.
- Developing a timeline for study activities that will address each research objective within the proposed funding period.
- Developing statistically sound evaluation models for the data to be collected and analyzed.
- Interacting cooperatively with appropriate CDC staff in all stages of the performance period.
- In addition to the formal annual reporting requirements, the PD(s)/PI(s) may be required to submit quarterly or biannual written reports as well as participate in quarterly or biannual conference calls with the CDC Technical Advisor to aid in his/her ability to regularly monitor performance against approved project objectives.

CDC staff have 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 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
- Regularly monitoring performance against approved project objectives and defined milestones.

Areas of Joint Responsibility include:

- Publication of research in scientific journals and on the CDC's website, as appropriate and warranted.
- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application, and the summary of reviewers' comments for the application, may be shared with the CDC staff who will provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC grant regulations and policies.

Additionally, a Scientific Program Officer in the NCHHSTP 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 grantee'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) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

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

    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
    - Research Aims: list each research aim/project

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

b) Leadership/Partnership: list project collaborations and describe the role of external partners.

    - Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these

findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

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

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

Additional reporting may be required quarterly or biannually during each budget period.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) 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 is 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 on the Payment Management System (PMS) can be found at https://pms.psc.gov.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm.

Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

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

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

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

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

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

Agency Contacts:

Scientific/Research Contact
Amy Yang, PhD.
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8836
Email: AYang@cdc.gov

Peer Review Contact
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

Financial/Grants Management Contact
Sharon Cassell
Office of Financial Resources
Office of Grants Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2939 Flowers Road, MS TV-2
Atlanta, GA 30341
Telephone: 770-488-2703
Email: zpr0@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 of Federal Regulations.

Public Health Service Act, Section 301(a) [42 U.S.C 241(a)] and Section 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended.