

Centers for Disease Control and Prevention

Center for Global Health

Advancing Public Health Research in Bangladesh

RFA-GH-24-033

03/08/2024

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

Center for Global Health
National Center for Chronic Disease Prevention and Health Promotion
National Center for Emerging and Zoonotic Infectious Diseases
National Center for Environmental Health
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
National Center for Immunization and Respiratory Diseases
National Center for Injury Prevention and Control
Office of Infectious Diseases

Notice of Funding Opportunity (NOFO) Title

Advancing Public Health Research in Bangladesh

Activity Code

U01 – Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-GH-24-033

Assistance Listings Number(s)

93.326

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to conduct high quality public health research and surveillance activities to support the government of Bangladesh and other partners to detect, prevent, and respond to disease threats. Research projects may be quantitative, qualitative, and /or mixed methods epidemiological studies, laboratory-based studies, or other types of research projects that focus on the following: a) Characterizing priority diseases in Bangladesh, b) Determining the most effective interventions and implementation approaches, and c) Measuring impact of public health efforts. All funded research projects should be conducted in partnership with the Government of Bangladesh and include clear mechanisms for advancing public health policy and practice at local, national, regional, and/or global levels.

Key Dates

Publication Date:

To receive notification of any changes to RFA-GH-24-033, 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:
12/14/2023
Not applicable

Application Due Date:
03/08/2024
03/08/2024

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 11:59 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:

04/15/2024

Secondary Review:
05/30/2024

Estimated Start Date:
09/30/2024

Expiration Date:
03/09/2024

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - 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 conduct high quality public health research and surveillance activities to support the government of Bangladesh and other partners to detect, prevent, and respond to disease threats. Research projects may be quantitative, qualitative, and /or mixed methods epidemiological studies, laboratory-based studies, or other types of research projects that focus on the following: a) Characterizing priority diseases in Bangladesh, b) Determining the most effective interventions and implementation approaches, and c) Measuring impact of public health efforts. All funded research projects should be conducted in partnership with the Government of Bangladesh and include clear mechanisms for advancing public health policy and practice at local, national, regional, and/or global levels.

Mechanism of Support: Cooperative Agreement

Funds Available and Anticipated Number of Awards: The estimated total funding available, including direct and indirect costs, for the entire **5**-year project period is **$22,000,000**. The number of awards will be up to **one**. 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) will be **$6,000,000** with individual awards ranging from **$0** to

$6,000,000 for the first year. The estimated total funding (direct and indirect) for the entire project period will be **$22,000,000**. The project period is anticipated to run from **[09/30/2024 to 09/29/2029]**.

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. Only one application per institution (normally identified by having a unique UEI number) is allowed.

Application Type. New

Application Materials. See Section IV.1 for application materials.

Section I. Funding Opportunity Description

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

1. Background and Purpose

With a population of more than 170 million people in a country the size of the U.S. State of Iowa, Bangladesh is the most densely populated country in the world (except for city-countries like Singapore). That density increases even more during the annual monsoon, when nearly 1/3 of the land mass is covered with water as the Ganges delta swells with rain and run-off from the Himalayas. With the help of development assistance, Bangladesh has reduced the poverty rate from over half of the population to less than a third, has achieved Millennium Development Goals for maternal and child health, and has made great progress in food security.

Scientists agree that Bangladesh is particularly susceptible to the emergence of novel influenza virus and other novel pathogens. In 2014, 2015 and 2016 the governments of both Bangladesh and the United States agreed to support an organized Global Health Security Agenda (GHSA), which is a coordinated effort among more than 64 nations to work together to detect, prevent, and respond to emerging infectious disease threats. As part of that effort, the U.S. Government focuses resources and technical support for achieving GHSA milestones of the 17 membership countries, including Bangladesh. The Centers for Disease Control and Prevention (CDC) has been working in Bangladesh for the last 50 years, with a primary focus of understanding infectious diseases and evaluating strategies that address global health threats. With the advent of the United States Government and the Government of Bangladesh's commitment to the GHSA, CDC research and public health projects continue to increase focus on activities that have strong

potential to result in changes to public health policy and practice, and improved health outcomes and global health security.

Healthy People 2030 and other National Strategic Priorities
While the Healthy People 2030 (HP2030) goals are generally specific to US domestic programs, the global health activities within this NOFO extend the national strategic priorities through the following HP2030 Global Health Objectives:

- Increase the number of individuals trained globally to prevent, detect, or respond to public health threats (GH-D01)
- Increase the number of globally important public health events that are tracked and reported (GH-D02)
- Increase laboratory diagnostic testing capacity, surveillance, and reporting globally (GH-D03)

The Department of Health and Human Services' (HHS) Global Health Strategy maintains three goals to support HHS' global health vision of a healthier, safer world:

- Protect and promote the health and well-being of Americans through global health action.
- Provide leadership and technical expertise in science, policy, programs and practice to improve global health.
- Advance United States interests in international diplomacy, development, and security through global health action.

Public Health Impact
The Public Health Impact of this proposed work will be high quality public health and implementation science research that will guide stakeholders to prioritize resources, develop policies, and implement practices and interventions that mitigate the impact of health threats on the Bangladeshi population and potentially globally. Research projects should be relevant to exploring strengthening surveillance capacity that results in a tiered laboratory system, strengthening Bangladesh's public health workforce, supporting effective emergency response capacities, and improving clinical care and prevention interventions. Improvements in these areas should increase the ability of the government of Bangladesh and other partners to detect, prevent, and respond to disease threats, to improve population health outcomes and reduce the risk of global pandemics.

Relevant Work
For more thank 50 years, the Centers for Disease Control and Prevention (CDC) has been working with Bangladesh, and often in close collaboration with the International Centre for Diarrheal Disease Research, Bangladesh (icddr,b), a premier global health research institution in Dhaka. CDC has awarded icddr,b four research cooperative agreements (FY2004-2009, FY2009-2014, FY2014-2019, FY2019-2024) which have supported research and surveillance activities in a broad range of technical and priority GHSA areas, and one non-research cooperative agreement (FY2014-2019). More than a hundred research projects and capacity building activities have been conducted jointly under the terms of these awards. While early activities focused on diarrheal disease, the collaboration has grown to encompass research and surveillance activities in areas ranging from emerging infectious diseases, influenza, polio vaccine immunogenicity

studies, One Health and antimicrobial resistance. Many of these efforts have had important impacts on public health policy practice, including providing evidence for updating of polio immunization guidelines, influenza surveillance and reporting to the World Health Organization (WHO), evidence for introduction of rotavirus vaccine, evidence supporting the feasibility and benefits of co-administration of oral polio and cholera vaccines in children under 1 year of age, and a much deeper understanding of the newly identified Nipah Virus. Building on the icddr,b-CDC joint efforts to support core capacity development in outbreak response and surveillance, CDC has also developed a direct-bilateral relationship with the Institute of Epidemiology Disease Control and Research (IEDCR) within the Bangladesh Ministry of Health and Family Welfare (MoHFW) to support research activities that facilitate the implementation of the GHSA. icddr,b has been a long-time, valuable partner of the Institute for Epidemiology, Disease Control and Research (IEDCR) within the MoHFW. icddr,b and IEDCR have established guidelines for effective collaboration on icddr,b-implemented surveillance, outbreak response, and relevant research projects.

Prospective applicants should refer to the following websites and related documents for additional information on CDC activities that support or relate specifically to this NOFO:

- Global Health Security Agenda – Prevent. Detect. Respond.
- CDC - Global Health
- Global Health Security | Division of Global Health Protection | Global Health | CDC
- Global Immunization Division | CDC
- Who We Are | NCEZID | CDC
- Immunization and Respiratory Diseases (NCIRD) Home | CDC

2. Approach

RESEARCH CATEGORIES Applicants may propose projects that focus on at least one of the following research categories. Projects may be proposed in one research category or can be a combination of the three categories: A, B, or C. Examples of projects are provided under each research category:

Category A: Characterize Priority Diseases in Bangladesh

Conduct research activities to determine burden, trends, etiology, and risk factors for priority diseases in Bangladesh. These research activities may be laboratory-focused, observational, epidemiological, or utilize other rigorous methods.

Examples of projects that characterize priority diseases include:

- Develop, maintain, or expand a multi-site sentinel surveillance system in Bangladesh to determine burden of disease, transmission dynamics, risk factors, relative contribution of different pathogens to disease syndromes, and/or control of infectious agents.
- Support the development or strengthening of laboratories and/or platforms used for etiologic investigation, evaluation of novel diagnostic assays for faster and easier detection, and characterization of pathogens.
- Develop and/or maintain one or more research sites to investigate and report the interactions between specific pathogens and underlying co-morbidities.

- Conduct research on the human-animal interface of zoonotic diseases and risks of transmission from animals to humans.
- Develop and test innovative solutions identified through research to develop early warning systems to report sentinel organisms in humans that can serve as an alert for multidrug resistant organisms and interventions for adequate antimicrobials.

Category B: Determine the Most Effective Implementation Approaches and Interventions

Conduct research to identify the most effective implementation approaches for responding to global public health threats and building global health security capacity. Examples of projects that address effective implementation approaches include:

- Conduct research to evaluate the effectiveness of different vaccine delivery methods, for example comparing immune responses to vaccinations provided on different schedules or when co-administered with other vaccinations.
- Conduct qualitative socio-cultural research and surveys of knowledge, attitudes, and practices related to infectious disease and the acceptance of interventions and prevention methods.
- Develop new interventions, evaluate the effectiveness of interventions, and/or make recommendations for scale-up of interventions designed to reduce the spread of disease (for example, IPC methods or poultry slaughtering methods).
- Develop and test new diagnostic or laboratory testing methods to build stronger laboratory, surveillance, and response capacity.

Category C: Measure Impact

Conduct research on the current capacity of the Bangladesh health system; examine impact of investments by donors for GHSA and International Health Regulation capabilities, or specific program effectiveness. Projects should lead to the development and/or improvement of national and regional policies and programs for disease prevention, monitoring and control. Examples of projects that measure impact include:

- Conduct evaluations of surveillance programs in Bangladesh to determine coverage rates, barriers, best practices, and effectiveness.
- Measure the impact of enhancements in public health surveillance in a country (in terms of outbreaks controlled, cases averted, time lags from specimen detection to collection etc.).
- Conduct research to estimate the direct and indirect costs, and document the economic burden of priority diseases and/or develop cost-effectiveness estimates of prevention and control programs for a priority disease.

Applicant may propose a variety of projects that address these disease areas and categories. Within each project, the applicants must submit separate Research Plans and Budgets. Applicant must provide assurance of coordinated management and administrative support. Applicant may propose new projects, as well as existing projects that were previously reviewed and approved.

For each project proposed, the focus should be on an identifiable public health concern or problem impacting health in Bangladesh. Applicant may propose new projects, as well as existing projects that propose new objectives and activities to address emerging diseases as well

as risk factors associated with the leading causes of death in Bangladesh. This may include disease surveillance, data collection, epidemiologic studies, laboratory-based studies, and the evaluation of interventions and/or control methods including therapeutic and preventative treatments.

This NOFO may fund health information systems infrastructure, including workforce and public health laboratories, to support specific strategies, activities, and outcomes described in this NOFO.

OVERALL MANAGEMENT PLAN

An overall management plan must be included as part of the General Administrative and Central Support Services proposal. The overall management plan must address the entire 5-year project period, including how the core objectives of the General Administrative and Central Support Services Teams (see Objectives/Outcomes section below) will be met. The plan must describe how the applicant will manage common resources and address any potential overlap of costs and activities. The plan should name the principal investigator or other key staff responsible for overall programmatic oversight. The principal investigator or other key staff responsible for overall programmatic oversight should be named. This overall plan should include the following:

- A central plan to achieve oversight and awareness of the geographical distribution of research projects to avoid any potential overlap in study sites and catchment areas. For example, through creating and maintaining a central map and/or database of study sites and their catchment areas for recently completed and ongoing CDC-funded studies (and non-CDC funded studies that are in proximity).
- A research workforce development plan to ensure a cadre of highly trained junior and early career investigators who are poised to become independent researchers to sustain the key research and surveillance programs initiated through prior CDC cooperative agreements. For example, 1) trainees supervised by key senior investigators are promoted for formal and informal research training opportunities; 2) pre-doctoral and post-doctoral research fellows are meaningfully engaged in all aspects of research development and implementation.
- A plan to ensure that projects' Translation Plans are implemented in a timely fashion to ensure the maximum impact. For example, through ensuring research findings with the potential for immediate public health practice and policy implications are shared with the appropriate Bangladeshi Government Offices and other relevant stakeholders expeditiously.
- A letter of support from the appropriate Bangladeshi Government Offices and external partners to document future collaboration to implement the proposed research program.

Objectives/Outcomes

Applicants may propose research projects in the first year of award that will contribute to strengthening the ability of the government of Bangladesh and other partners to detect, prevent, and respond to disease threats through high quality public health research and surveillance activities. Specifically, the projects should focus on: a) determining burden, trends, etiology, and risk factors of priority diseases in Bangladesh, b) developing and evaluating interventions and diagnostics, c) evaluating the effectiveness of vaccinations d) informing global policy, and e)

strengthening the Government of Bangladesh's surveillance, laboratory and outbreak response capacity.

Applicants may submit an application on one or more of the following eligible **disease areas**:

1. Acute febrile illness (AFI)
2. Encephalitic illness (including Nipah Virus and Japanese Encephalitis)
3. Antimicrobial resistance (AMR) and/or healthcare-associated infections (HAI)
4. Infection Prevention and Control (IPC) and Surgical Site Infection (SSI) stewardship activities
5. Vaccine-preventable diseases
6. Influenza and other respiratory illnesses
7. Zoonotic diseases
8. One Health studies addressing antibiotic resistance associated.
9. Other public health issues of global, regional and/or local importance

CDC's funding is largely disease specific, as such funding decisions will be based on alignment with a particular disease area.

ADMINISTRATIVE AND CENTRAL SUPPORT SERVICES OJECTIVES

- Effective management of common resources to avoid any potential overlap of costs and activities.
- Effective budgeting and expense forecasting on a per project basis, to include utilization of templates provided by CDC as guides to prepare routine expense reports for each project and the Administrative and Central Support Teams. Reports to include:
    - Quarterly burn rate reports.
    - Quarterly projection reports, to include the approved budget (new and carryover funds), and projections of personnel costs, recurring and anticipated expenses.
- Proactive coordination with the CDC, Global Health Center, Extramural Research Program Office regarding expense reporting through routine (for example, quarterly) budget review calls.
- Effective oversight of the necessary registrations, including icddr,b's Federal Wide Assurance (FWA), to ensure registrations remain active for the duration of the award.
- Effective oversight, management and documentation of study protocol review by the icddr,b Institutional Review Board (IRB) to ensure the timely annual renewal of approved studies.
- Effective oversight and central documentation of the certification of annual Human Subjects Research Training for study key personnel and IRB approvals.
- Proactive coordination with CDC Programs and the Global Health Center, Extramural Research Program Office personnel to ensure the timely and efficient submission of requests to release human subjects research restrictions.
- Effective oversight of a Material Transfer Agreement (MTA) with CDC. Please note: CDC Global Health Center, Extramural Research Program Office personnel should be given the opportunity to review any changes to approved project titles or project IDs prior to implementing a change. For each project a table summarizing the samples to be transferred should be included. Table headings should include the species, sample type,

sample volume and number of vials. Any amendments to an existing MTA should be made with track changes for to capture all changes.

- Comprehensive progress reporting through completion of all sections of the annual and final Research Performance Progress Reports (RPPRs), including personnel effort reporting, documentation of human subject research ethics training for new key personnel, and reporting on the core responsibilities and functions of the Administrative and Central Support Services teams.
- Effective oversight and awareness of the geographical distribution of research projects to avoid any potential overlap in study sites and catchment areas.
- Robust research workforce development to ensure a cadre of highly trained junior and early career investigators are poised to become independent researchers and sustain the key research and surveillance programs initiated through prior CDC cooperative agreements.

Target Population

The prospective applicant must identify the target populations to be addressed through this NOFO, including risk factors for disease and impact of increased diagnostics and surveillance by population type. The prospective applicant should use data generated under this NOFO to identify communities disproportionately affected by different infectious diseases, and propose activities/interventions to reduce or eliminate these disparities. The applicant should describe how the activities under this NOFO will be inclusive of all affected populations.

Collaboration/Partnerships

Collaborations with a broad range of partners will be increasingly critical to generate data, make recommendations, and implement those recommended actions and policies relevant to the Global Health Security Agenda. The successful applicant must maintain close working relationships with the Bangladesh MoHFW, particularly the Institute for Epidemiology Disease Control and Research; the Bangladesh Ministry of Fisheries and Livestock (MoFL), and the Bangladesh Ministry of Agriculture (MoA). In addition, the applicant should maintain relationships with other stakeholders such as the WHO other multinational health organizations (World Organisation for Animal Health, Food and Agriculture Organization of the United Nations, and United Nations International Children's Emergency Fund). All proposed activities should align with the goals of the GHSA and/or Bangladesh’s strategic priorities and identified gaps, for example those outlined in the sector planning process or the Joint External Evaluation. Applicants are encouraged, but not required, to collaborate with academic and other health related organizations on research projects in which partnership(s) would add value to the project. Project proposals that require engagement and collaboration with partners should include the appropriate letters of support.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a **5**-year research project period. The grantee will establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application’s project plan, and describe the development and implementation of project performance measures based on specific programmatic objectives.

Performance will be continuously monitored during the life of the award, through routine meetings held between the recipient and CDC. The recipient will work with CDC and other

global partners as appropriate to develop and implement an evaluation plan and performance measures after award. Some examples of potential performance measures for a selection of categories are listed below:

EPIDEMIOLOGIC AND LABORATORY RESEARCH, AND IMPLEMENTATION SCIENCE:

- *Number of protocols launched on planned timeline*
- *Proportion of participants recruited on time*
- *Proportion of studies completed on time*

ADMINISTRATIVE AND CENTRAL SUPPORT SERVICES:

Fiscal management Programs must use funding to support activities in alignment with the requirements of this NOFO. Programs must develop and maintain systems for sound fiscal management, including: monitoring the cooperative agreement award and program contracts and grants, ensuring the funds are expended in support of approved activities. Some potential performance measures include:

- *Implementation of necessary administrative standard operating procedures*
- *Number of key personnel with lapse in Human Subjects Research Ethics training certification*
- *Number of IRB protocol deviations*
- *Number of planned routine meetings with key stakeholders scheduled and completed*
- *Timely submission of quarterly financial reports with clear cost allocation breakdown*
- *Timely submission of progress reports and dissemination to key stakeholders*
- *Number of staff completed annual human subjects research training*
- *Number of labs maintaining required level of lab accreditation*
- *Number of necessary laboratory standard operating procedures drafted, reviewed and approved*
- *Implementation and utilization of cost allocation plans*
- *Number of study sites and catchment areas with activities reflected on a central map and or database*
- *Number of research projects engaging trainees and early career investigators*
- *Number of studies included in a centrally maintained map and/or database of the study sites and their catchment areas for recently completed and current CDC-funded studies (and non-CDC funded studies that are in proximity)*
- *Number of projects with meaningfully engaged junior or early-career investigators.*
- *Number of studies whose findings had impact to local, regional and global public health practice and policy*
- *Number of IRB protocols with exclusion criteria to avoid recruitment of participants into multiple studies or describes an approach to manage the potential issue in other ways*

Translation Plan

The applicant should describe plans for how research and scientific findings will be reported and disseminated (e.g., peer-reviewed journals, scientific presentations, reports, meetings and conferences) and specify how these activities are integrated into the project plans. Applicant

should use appropriate scientific journals to disseminate research findings to the broader scientific community in conjunction with CDC scientists. Applicant should present important evaluation and research findings at relevant international scientific meetings and conferences. Applicant should describe the processes and mechanisms or oversight to ensure that research findings with the potential for immediate public health practice and policy implications are shared with the appropriate Bangladeshi Government Offices and other relevant stakeholders expeditiously. The translation of findings should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, health care institutions, professional organizations, community groups, researchers, and other potential users.

Questions to consider in preparing this section include:

1. How will the scientific findings inform future public health policies or practices at the local and national level?

- *What are some recommendations could come from my research questions?*
- *How does my study respond to priorities of the government or other stakeholders?*
- *How could my findings inform future scientific inquiry?*

2. Who are the key stakeholders in the government who could implement the recommendations or use the information that comes out of my research study?

3. How can I design my project so that stakeholders will be interested in the results of my project and be more likely to pay attention to the findings?

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:
$22,000,000
Estimated Total Annual Budget Period Funding:

- Year 1: $6,000,000
- Year 2: $4,000,000
- Year 3: $4,000,000
- Year 4: $4,000,000

- Year 5: $4,000,000

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 MTDC 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.

Anticipated Number of Awards:
1
Estimated total funding available for first year (first 12 months), including direct and indirect costs: $6,000,000

Estimated total funding available for entire project period, including direct and indirect costs: $22,000,000

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).

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

Award Ceiling:
$6,000,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (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:
25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

2. Foreign Organizations

Foreign Organizations **are** eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm UEI by viewing the organizational registration on SAM.gov. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

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

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

3. Additional Information on Eligibility

icddr,b (formally International Centre for Diarrhoeal Disease Research, Bangladesh) is the sole eligible applicant.

4. Justification for Less than Maximum Competition

icddr,b is an international not-for-profit research institution headquartered in Dhaka, Bangladesh and has a long history of working on the frontlines of global health and producing high quality and impactful science. In addition, the institution maintains the largest diarrheal hospital in the world and the longest running demographic surveillance system in Asia. This grantee received an approved single eligibility status for all prior research and non-research cooperative agreements—including in 2004, 2009, 2014, and 2019 and is uniquely qualified for the following:
1. CDC has a 45-year history of collaborations with icddr,b. This includes 4 past research cooperative agreements one non-research cooperative agreement. Findings from multiple studies have informed public health practice both in Bangladesh and around the world (for example, evidence for updating polio immunization guidelines, the feasibility and benefits of co-administration of oral polio and cholera vaccines in children <1 year of age, introduction of rotavirus vaccination in Bangladesh, furthermore influenza surveillance activities provide weekly uploads to the WHO and have provided nationally representative data to the WHO's Global Influenza Surveillance and Response System (GISRS) which helps in selecting and updating influenza vaccine candidates. CDC has funded icddr,b to establish biosafety and biosecurity program and safe and secure specimen transport system for flu surveillance program in the country with the approval from the Director General of Health Services.
2. icddr,b has been a long-time partner of the Ministry of Health and Family Welfare, CDC's

primary Global Health Security Partner. icddr,b and the Institute of Epidemiology Disease Control and Research (IEDCR) - part of the Ministry of Health and Family Welfare – have well established guidelines for a effective collaboration for all icddr,b-implemented surveillance, outbreak response, and applicable research projects. icddr,b also has a long collaboration with the Expanded Program for Immunization (EPI) at the National and local level for implementation of vaccine clinical trials. icddr,b also has close connections with Dhaka Medical College Hospital which is critical for many ongoing studies, including in GHSA priority areas such as antimicrobial resistance.
3. icddr,b is the only non-diplomatic partner that CDC is aware of that has the legal authority and operational expertise to process the import of laboratory supplies and reagents, including time sensitive reagents. Similarly, icddr,b has existing agreements with major biomedical transportation organizations and maintains an updated material transfer agreement (MTA) with CDC for the shipping of swabs, blood, serum and DNA.
4. CDC Programs been working closely with the icddr,b Genomic Center to conduct whole genome sequencing for multiple projects using state of the art sequencing systems and highly trained and efficient bioinformatics team.
5. Until 2014, icddr,b was the only institution within the country to have a certified BSL-3 laboratory. Unfortunately, it was damaged in an earthquake and icddr,b is now following BSL-2+ guidelines and all international standards for biosafety and biosecurity. icddr,b is in the process of rebuilding their BSL-3 laboratory and again will soon be the only institution with a BSL-3 laboratory. Furthermore, the clinical microbiology laboratory meets the international standards of quality and is ISO 15189-2012 accredited. They have a strong and active institutional biosafety committee and Senior biosafety officer. icddr,b is the most biosafety capable institution in the country and the work under this NOFO will be critical for the Health Security Agenda, including ongoing studies on pathogens such as Nipah virus which has pandemic potential, C. auris, influenza and the testing of human, avian and bovine surveillance samples with unknown etiology. Additionally, surveillance activities contemplated under this NOFO detect and isolate high-consequence pathogens whose handling and storage require advanced biocontainment skills and capacity. To CDC’s knowledge, icddr,b is the only institution in Bangladesh with the capability to handle such pathogens according to international biosecurity standards.
6. Without continuation of this mechanism which now includes 11 CDC Programs, the relationship and much of the investment over the last 20 years will be lost and important progress and gains in key Global Health priorities will be halted. In addition, the CDC office is on the icddr,b compound and CDC's operations would be directly impacted if this mechanism were to disappear. Over the last 20 years, CDC has initiated several long-term research projects with icddr,b that we hope will continue beyond FY 2024, including 3 syndromic hospital-based sentinel surveillance platforms, a cohort of children examining respiratory outcomes, and ongoing outbreak responses to disease clusters in partnership with the government. Past CDC investments have strengthened critical scientific credibility and expertise among icddr,b staff and ensured expanded laboratory capacity and established study clinics that are used sometimes exclusively by CDC Programs, for example several immunization clinics along with skilled personnel are critical for the implementation of polio vaccine studies that are crucial to inform vaccination strategies for polio eradication. Several CDC Programs leverage icddr,b’s long-term community cohorts which are essential for studies that assess changes over time and provide an in depth understanding of a given population with regard to for example, antibiotic resistance – a

Health Security Agenda initiative.
7. icddr,b has a long history of employing both third country nationals and Bangladeshis with strong scientific skills - a requirement for the effective implementation of the NOFO activities.

5. Responsiveness

Applicant must provide letters of support from the appropriate Bangladeshi Government Ministries and external partners to document their ongoing collaboration for the implementation of the research program.

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).
- 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 Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 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 UEI 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.

Only one application per institution (normally identified by having a unique UEI number) is allowed.

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 before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

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 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.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

Applicant may propose a variety of projects that address these disease areas and categories. Within each project, the applicants must submit separate Research Plans and Budgets. Applicant

must provide assurance of coordinated management and administrative support. Applicant may propose new projects, as well as existing projects that were previously reviewed and approved.

For each project proposed, the focus should be on an identifiable public health concern or problem impacting health in Bangladesh. Applicant may propose initiating new projects, or existing projects that propose new objectives and activities to address emerging diseases as well as risk factors associated with the leading causes of death in Bangladesh. This may include disease surveillance, data collection, epidemiologic studies, laboratory-based studies, and the evaluation of interventions and/or control methods including therapeutic and preventative treatments.

Since this is an **umbrella cooperative agreement** with multiple programs, applicant is recommended to follow the additional instructions below:

Please submit a summary of the submission in the following table format.

Project Title	Project ID	Project Duration	Year 1 Budget	New or Existing

- Please separate projects by program. If programs have multiple projects, please ensure that each project has all the relevant information (2- 16 in PHS398). Individual budgets are required along with the justification.
- Include a separate proposal to thoroughly describe the core responsibilities and functions of the Administrative and Central Support Services teams, including a budget and budget justification. These should be uploaded as a separate plan under the Appendix.
- Please identify if project is existing **(from the previous years) or new.**
- Ongoing projects that have been peer reviewed previously and could not be completed due to technical challenges at the field study site, delay in IRB approvals or because their objectives could not be met during the previous CoAg period could be exempted from peer review. Please indicate these projects are existing/ongoing. *Please ensure that the title is the same as the original submission and the Project ID is included.*
- All new projects will be peer reviewed.
- If all the project proposals from the various programs cannot be all uploaded in the given page limitation, please upload them under Appendix.

Administrative and Central Support Services Costs:

- Direct Costs to for Administrative and Central Support directs will be approved up to 20% of each annual budget up to $3,000,000. For funding above **$3,000,000 (inclusive of carryover of prior year unobligated funds)** direct costs up to 5% could be approved for Administrative and Central Support.
- As for any direct cost, direct costs supporting Administrative and Central Support activities should follow the standard Cost Principles described in the following Code of Federal Regulations (CFRs):
    - 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
    - 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

- All administrative and central support costs included in the budget as directs costs should be allocated clearly and itemized in each Project budget and summarized in a separate categorical budget and budget justification.

3. Letter of Intent

Number Of Days from Publication 0

12/14/2023
N/A

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 before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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.

N/A

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 20 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 20 PDF files with a maximum of 150 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 date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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 03/08/2024

03/08/2024
Electronically submitted applications must be submitted no later than 11:59 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.

Additional Funding Restrictions:

1) 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.

2) Funds relating to the conduct of research involving human subjects will be restricted until Human Subjects Education Requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct or research involving human subjects.

3) 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.

4) 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).

5) 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 USG funding, or loss of future US Government (USG) funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution,

consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

6) 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.

7) 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).

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 UEI.

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.

Administrative and Central Support Services Costs:

- Direct Costs to for Administrative and Central Support directs will be approved up to 20% of each annual budget up to $3,000,000. For funding above **$3,000,000 (inclusive of carryover of prior year unobligated funds)** direct costs up to 5% could be approved for Administrative and Central Support.
- As for any direct cost, direct costs supporting Administrative and Central Support activities should follow the standard Cost Principles described in the following Code of Federal Regulations (CFRs):
    - 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
    - 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
- All administrative and central support costs included in the budget as directs costs should be allocated clearly and itemized in each Project budget and summarized in a separate categorical budget and budget justification.

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

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

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

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

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://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?

ADMINISTRATIVE AND CENTRAL SUPPORT SERVICES

- *Does the proposal include an appropriate and adequate administrative structure with an internal organization capable of managing program activities?*
- *Does the proposal clearly delineate procedures and plans for financial and research administration?*
- *Is a strategic plan outlined which identifies the short-term and long-term goals of the Administrative and Central Support Services, and a well-defined process for implementing the activities to achieve the goals set?*
- *Does the administrative structure facilitate a highly integrated program of financial management, data management systems, and education on topics such as human subjects' protection, ethics, and quality control?*
- *Does the administrative structure enable oversight of the geographical distribution of research projects to avoid any potential overlap in study sites and catchment areas?*

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?

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?

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?

ADMINISTRATIVE AND CENTRAL SUPPORT SERVICES

- *Are potential problems, alternative strategies, and benchmarks for success presented?*
- *Is the overall administration strategy well-reasoned and appropriate to accomplish the outcomes?*
- *Does the application describe a plan to determine the impact, quality, and effectiveness of the Administrative and Central Support Services?*
- *Is the plan to organize communications, group meetings, and/or teleconferences adequate and appropriate?*
- *Are the plans for coordination, problem identification and resolution, and establishment of a strong collaborative environment for the program appropriate?*
- *Are the plans for resource allocation within the program adequate and appropriate?*
- *Are the plans for communication and collaboration with other programs adequate?*
- *Is a plan to ensure research workforce development to ensure a cadre of future independent researchers in order sustain key research and surveillance programs initiated through this and prior CDC cooperative agreements?*
- *Is there a plan to ensure studies avoid recruitment of participants into multiple studies? For example, through inclusion and exclusion criteria.*

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?

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/additional-requirements/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/women/research/index.htm) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

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

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

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

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

3. Additional Review Considerations

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

Additional review considerations is not applicable with this nofo.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plan(s)

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additional-requirements/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 budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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 all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

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

will receive a second level of review. The following will be considered in making funding 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 UEI, 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: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: 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-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.

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: *https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75*

To view brief descriptions of relevant CDC requirements visit:
https://www.cdc.gov/grants/additional-requirements/index.html

Administrative and Central Support Services Costs:

- Direct Costs to for Administrative and Central Support directs will be approved up to 20% of each annual budget up to $3,000,000. For funding above **$3,000,000 (inclusive of carryover of prior year unobligated funds)** direct costs up to 5% could be approved for Administrative and Central Support.
- As for any direct cost, direct costs supporting Administrative and Central Support activities should follow the standard Cost Principles described in the following Code of Federal Regulations (CFRs):
    - 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
    - 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
- All administrative and central support costs included in the budget as directs costs should be allocated clearly and itemized in each Project budget and summarized in a separate categorical budget and budget justification.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy 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: https://www.plainlanguage.gov/.

Employee Whistleblower Rights and Protections Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition

that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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/additional-requirements/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/additional-requirements/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 recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access **https://www.cdc.gov/grants/additional-requirements/ar-25.html**
- 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 support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC 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.

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

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access **https://www.cdc.gov/grants/additional-requirements/ar-25.html**
- Conduct routine site visits to icddr,b for the purpose of monitoring performance and compliance with the Terms and Conditions of the award
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Additionally, a Scientific Program Officer in the Global Health Center 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.

Areas of Joint Responsibility include: None; all responsibilities are divided between the awardee and CDC staff as described above.

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 submit:

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 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after 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:

ADMINISTRATIVE AND CENTRAL SUPPORT SERVICES

- Include in section **'B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?'** of all annual and final Research Performance Progress Reports (RPPRs) a thorough description of the core responsibilities and functions of the Administrative and Central Support teams.

- In section **'B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?'** of all annual and final RPPRs include the accomplishments of the administrative and central support teams.
- In section **'D.4 WHAT INDIVIDUAL HAVE WORKED ON THE PROJECT?'** of all annual and final RPPRs include all personnel supported with the award, inclusive of the administrative and central support personnel and their effort.
- For all annual and Final RPPRs include:
    - Current IRB approvals for all continuing projects
    - For new study staff documentation of training in
    - A centrally maintained map and/or database of the study sites and their catchment areas for recently completed and current CDC-funded studies (and non-CDC funded studies that are in proximity).
- Using templates provided by CDC as a guide prepare routine expense reports for each project and the Administrative and Central Support Teams, including:
    - Quarterly burn rate reports.
    - Quarterly projection reports by budget year, to include the approved budget (new and carryover funds), and projections of personnel costs, recurring and anticipated expenses.

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 budget period. 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 period of performance. 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).

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

Scientific/Research Contact

Lata Kumar

Global Health Center (GHC), Office of Director

Telephone: 404-639-7618

Email: lek7@cdc.gov

Peer Review Contact

Hylan Shoob

Global Health Center (GHC), Office of Director

Telephone: 404-639-7618

Email: hms4@cdc.gov

Financial/Grants Management Contact

Manal Ali

Office of Financial Resources (OFR)/ Office of Grants Services

Telephone: 770-488-2863

Email: aen4@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.

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