

Centers for Disease Control

National Center for Immunization and Respiratory Diseases Extramural Research Program Office

Public Health Epidemiology of Influenza Virus Infection and Control in China
RFA-IP-18-004
Application Due Date: 03/21/2018

Public Health Epidemiology of Influenza Virus Infection and Control in China
RFA-IP-18-004
TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Immunization and Respiratory Diseases Extramural Research Program Office (NCIRD ERPO)

Notice of Funding Opportunity (NOFO) Title

Public Health Epidemiology of Influenza Virus Infection and Control in China

Activity Code

U01 - Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-IP-18-004

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

93.083

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to partner with the Chinese Center for Disease Control and Prevention (China CDC) to support enhanced influenza surveillance and applied research to better define the global risk of novel and seasonal influenza virus infections in humans and animals in China, the region and the world. The scope of research performed will include, but will not be limited to, activities that: a) determine the impact of influenza among vulnerable populations; b) assess the value of antiviral medications, vaccines and other mitigation strategies, and c) support and guide seasonal epidemic and pandemic influenza prevention and control studies. Research activities for the prevention and control of novel influenza viruses and pandemic preparedness activities will be aimed at preventing and controlling the spread and transmission of novel influenza viruses to other countries, including the United States. Continued monitoring, detection, and reporting of these novel influenza viruses in China will advance efforts to inform global health infection control policies and prevent and control seasonal epidemic and pandemic influenza in countries around the world.

Key Dates

Publication Date:

To receive notification of any changes to RFA-IP-18-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is

	needed for this service.
Letter of Intent Due Date:	**01/23/2018**
Application Due Date:	**03/21/2018**

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

Scientific Merit Review:	**05/15/2018**
Secondary Review:	**06/07/2018**
Estimated Start Date:	**09/30/2018**
Expiration Date:	**03/22/2018**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

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

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

Executive Summary

- **Purpose:** The purpose of this Notice of Funding Opportunity (NOFO) is to partner with the Chinese Center for Disease Control and Prevention (China CDC) to support enhanced influenza surveillance and applied research to better define the global risk of novel and seasonal influenza virus infections in humans and animals in China, the region and the world. The scope of research performed will include, but will not be limited to, activities that: a) determine the impact of influenza among vulnerable populations; b) assess the value of antiviral medications, vaccines and other mitigation strategies, and c) support and guide seasonal epidemic and pandemic influenza prevention and control

studies. Research activities for the prevention and control of novel influenza viruses and pandemic preparedness activities will be aimed at preventing and controlling the spread and transmission of novel influenza viruses to other countries, including the United States. Continued monitoring, detection, and reporting of these novel influenza viruses in China will advance efforts to inform global health infection control policies and prevent and control seasonal epidemic and pandemic influenza in countries around the world.

- **Mechanism of Support:** U01 - Research Project - Cooperative Agreement
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is $10,000,000. The anticipated number of awards will be one. Awards issued under this NOFO are contingent upon availability of funds and a sufficiently meritorious application. 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 a maximum of $2,000,000 with an individual award ranging from $1,000,000 to $2,000,000 for the first year. The estimated total funding (direct and indirect) for the entire project period will be a maximum of $10,000,000. The project period is anticipated to run from 9/30/2018 to 9/29/2023.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type.** New.
- **Application Materials.** See Section IV. 1 for application materials. Please note that **Form E** is to be used when downloading the application package.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Sections 301(a) [42 U.S.C. 241(a)] and 307 [42 U.S.C. 242l]

1. Background and Purpose

The National Center for Immunization and Respiratory Diseases (NCIRD), Influenza Division (ID), seeks to initiate a cooperative agreement with the Chinese Center for Disease Control and Prevention (China CDC), Beijing, China. The purpose of this collaboration is to support enhanced influenza surveillance and applied research to better define the global risk of novel and seasonal influenza virus infections in humans and animals in China, the region and the world. The scope of research performed will include, but will not be limited to, activities that: a) determine the impact of influenza among vulnerable populations; b) assess the value of antiviral medications, vaccines and other mitigation strategies, and c) support and guide seasonal epidemic and pandemic influenza prevention and control studies. Research activities for the prevention and control of novel influenza viruses and pandemic preparedness activities will be aimed at preventing and controlling the spread and transmission of novel influenza viruses to other countries, including the United States. Continued monitoring, detection, and reporting of these novel influenza viruses in China will advance efforts to inform global health infection control policies and prevent and control seasonal epidemic and pandemic influenza in countries around the world.

In 1997, the highly pathogenic avian influenza A (H5N1) virus emerged in China and resulted in several outbreaks in poultry and infections in humans that affected other countries in Southeast Asia. The last human infections with A (H5N1) virus in China were in 2016. Since 2003, there have been 53 human infections with A (H5N1) virus in China and, of those, 31 (59%) have died. In 1998, the National Health and Family Planning Commission in China also reported human infections with avian influenza A (H9N2) virus. Whereas the A (H9N2) influenza virus tends to cause milder illness in humans than the A (H5N1) virus, it continues to circulate. To date, there have been 34 human infections reported from China out of a total 41 reported worldwide.

In 2013, the first human infections with avian influenza A (H7N9) virus were reported from China. Through five annual epidemic periods, approximately 1,561 human infections were reported. Of those, approximately 90% resulted in severe illness and 40% died. Of the 1,561 infections, some sporadic detection with associated travel to China has been detected in other countries. Whereas human-to-human transmission is rare, and there has been no evidence of sustained transmission between humans, vigilance in the detection and testing of these viruses is critical to monitor changes in the virus that could make populations within and outside of China at risk for infection. Since the emergence of A (H7N9) virus, human infections of avian influenza A (H5N6), A (H10N8) and A (H6N1) viruses have also been detected and reported in China. Supporting China CDC in their efforts to monitor, detect, control, and prevent infections in humans is critical to preventing the worldwide spread of A (H7N9) and other novel influenza viruses currently circulating in China. The continued detection of novel viruses in China, coupled with the possibility of genetic mutations, or re-assortment with constantly circulating human influenza A viruses, underscores the importance of continuous monitoring and the development of an evidence-base for best practices related to novel influenza virus detection, preparedness, response, and mitigation within the country.

In Asia, China is uniquely positioned to conduct implementation research to assess risks associated from seasonal and novel influenza viruses and to evaluate the benefit and effectiveness of influenza vaccination and other prevention strategies in vulnerable populations. China CDC

houses a WHO-designated National Influenza Center and also serves as a WHO Collaborating Center for Influenza. The China CDC National Influenza Center regularly performs WHO and CDC proficiency panels, shares viruses with international WHO Collaborating Centers for Influenza and the Global Influenza Surveillance and Response System, and has the capacity to rapidly identify novel viruses such as, but not limited to, influenza A (H5N1) and A (H7N9) viruses. China CDC has also published guidelines on seasonal influenza vaccination among high risk groups. Recommended target groups for influenza vaccination in China follow the WHO Strategic Advisory Group of Experts (SAGE) recommendations for influenza vaccine and include: pregnant women, young children, the elderly, healthcare workers and persons with chronic diseases. Despite an existing influenza vaccination policy, influenza vaccination coverage remains at less than 2% for most target groups. This demonstrates the need for additional data to support increased vaccine supply and uptake.

Seasonal influenza vaccine coverage is higher in some municipalities and regions of China that have local policies for vaccinating certain at-risk populations. In Beijing, for example, annual seasonal influenza vaccination is offered free of charge to adults aged 60 years and older and to school children. Coverage in these high risk groups approaches 50% in Beijing. Having a system in place for seasonal vaccination will facilitate use of a pandemic vaccine, if and when it is needed. China is also one of the few middle-income countries with several local vaccine manufacturers who are currently developing pandemic influenza vaccines. In 2015, one of China's local biological manufacturers became the first to produce a WHO pre-qualified seasonal influenza vaccine. This allowed the donation of influenza vaccine from China to several resource-poor countries.

CDC's Influenza Division has collaborated with China CDC for more than 20 years. Activities include conducting influenza surveillance to better understand influenza seasonality, determining risk factors for severe disease, evaluating risk factors for transmission of novel influenza viruses at the animal-human interface, and estimating morbidity and mortality attributable to influenza virus infections. However, information on risk of influenza, and effectiveness of influenza vaccination and other prevention measures in vulnerable populations (e.g., pregnant women, persons with underlying medical conditions, the elderly, infants, and healthcare workers), is still limited. In addition, few data are available on the epidemiology and risk of infection with avian influenza A (H7N9) virus and the effectiveness of mitigation strategies. Addressing these gaps will inform global assessment of the risk posed by novel influenza viruses with pandemic potential and decisions about the need for influenza vaccine development, procurement, and stockpiling for target groups. Enhanced surveillance, program evaluation and research, conducted as part of this cooperative agreement, will seek to fill these gaps in our understanding of seasonal and novel influenza epidemiology in Asia.

Healthy People 2020 and other National Strategic Priorities

Not applicable.

Public Health Impact

Defining the risk of novel and seasonal influenza virus infections in humans and animals through influenza surveillance, vaccine program evaluations, and special studies among vulnerable populations is critical to maintaining preparedness to detect and respond to seasonal influenza epidemics and pandemics. Likewise, assessing the safety and value of influenza and other

respiratory pathogen vaccines, antiviral medications, and other mitigation strategies in vulnerable populations is important to ensure acceptability and feasibility of influenza and other respiratory pathogen prevention strategies and to optimize strategies to reduce the burden of associated illness. Finally, identifying optimal strategies for vaccine delivery and improved risk communications will improve the implementation of existing influenza policies and guidelines.

To date, China is the only country with ongoing circulation of avian influenza A (H7N9) virus in poultry, the environment, and humans. In addition to this virus, other avian influenza viruses have been detected in humans in China in the last five years including A (H6N1), A (H9N2), A (H5N1), and A (H10N8) viruses. There is ongoing concern that the next pandemic of influenza could emerge in China, posing a world-wide risk of infection in people. Defining the risk of novel and seasonal influenza virus infections in humans and animals by strengthening surveillance for influenza viruses and conducting program evaluations and special studies among vulnerable populations, is critical to maintaining preparedness to detect and respond to influenza pandemics and seasonal influenza epidemics. Likewise, assessing the safety and effectiveness of influenza vaccines, antiviral medications, and other mitigation strategies in vulnerable populations is important to: 1) ensure acceptability and feasibility of influenza prevention strategies and 2) develop strategies to reduce the burden of influenza-associated illness. Information obtained through collaborations with China expedite information sharing and are critical to trigger the rapid development of candidate vaccine viruses at CDC. These candidate vaccine viruses can be used for vaccine production, clinical trials, stockpiling and other pandemic preparedness purposes based on ongoing public health risk assessment.

Relevant Work

1. World Health Organization Influenza Surveillance and Monitoring. http://www.who.int/influenza/surveillance_monitoring/updates/latest_update_GIP_surveillance/en/
2. World Health Organization, Human infection with avian influenza A (H7N9) virus – China. http://www.who.int/csr/don/07-august-2017-ah7n9-china/en/
3. CDC National Center for Immunization and Respiratory Diseases, Influenza Division International Program. https://www.cdc.gov/flu/international/program/index.htm
4. CDC, Asian Lineage Avian Influenza A (H7N9) Virus https://www.cdc.gov/flu/avianflu/h7n9-virus.htm
5. RFA-GH-17-005: Conducting Public Health Research in China. https://www.grants.gov/web/grants/view-opportunity.html?oppId=292309
6. RFA-IP-16-1605: Maintenance of Influenza Surveillance Capacity by National Health Authorities Outside the United States. https://www.grants.gov/web/grants/view-opportunity.html?oppId=283956

The activities described in this NOFO build upon more than 20 years of laboratory and surveillance capacity building. CDC currently provides funding to China through several Cooperative Agreements, including RFA-GH-17-005 and RFA-IP-16-1605, to support seasonal influenza surveillance activities. The activities stipulated in this NOFO build upon this laboratory and research capacity by supporting new activities to: 1) enhance novel influenza virus surveillance and evaluation interventions that might be used during outbreak responses, and 2) test mitigation and control strategies to be employed during pandemics.

2. Approach

To accomplish the goals of this NOFO, the applicant organization should submit a research application that addresses one or more of the public health issues and priorities identified under the Objectives/Outcomes outlined below.

Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

Objectives/Outcomes

- Assess and enhance surveillance and laboratory capacity to rapidly and reliably identify and respond to novel influenza viruses with pandemic potential.
- Determine the disease and economic burden of influenza illness among vulnerable populations in China including, but not limited to, older adults, individuals with chronic health conditions, pregnant women, children less than 5 years of age, healthcare workers, and workers in the poultry industry.
- Evaluate possible improvements to the prevention and control of novel avian influenza viruses in commercial poultry settings.
- Assess the potential value of increasing influenza vaccination coverage among vulnerable populations in China. These might include evaluations and studies of "second generation" influenza vaccines (e.g., live attenuated influenza, intradermal influenza, high dose, adjuvanted, and cell-based influenza vaccines) that have the potential to offer broader, or longer lasting, immunity and/or improved immune response.
- Assess the value of novel influenza vaccination and other influenza prevention, treatment, and mitigation strategies (e.g., antiviral medications, non-pharmaceutical interventions) through program evaluations. Assessments might also include observational studies of existing public-sector programs, phase IV demonstration projects, or intervention studies among subpopulations at high risk of complications for influenza illness and where effectiveness/efficacy might be reduced (e.g., older adults).
- Assess communication and community outreach strategies to improve influenza vaccine acceptability and uptake, particularly in vulnerable populations.
- Define the risk of novel and seasonal influenza virus infections in humans and animals, especially among populations with increased exposure to novel viruses or vulnerable populations.
- Assess the safety of influenza vaccines in subpopulations by monitoring adverse events following immunization, or conduct special studies assessing the impact of influenza vaccine or antiviral treatment.
- Estimate the direct and indirect economic burden of influenza disease among a range of different subpopulations, including assessment of cost-effectiveness of influenza vaccination for priority groups.

Research performed under this NOFO will include regular dissemination and reporting of surveillance and research findings through: 1) continued participation in the Global Influenza Surveillance and Response System (GISRS) by routinely sharing quality specimens with other

WHO Collaborating Centers and by sharing data through WHO electronic systems; 2) making regular data available to partners within the country through surveillance reports or website summaries; and 3) publishing results of research studies in peer-reviewed scientific journals in a timely manner (i.e., within 12 months of study completion).

Target Population

The target population includes all migrant or permanent residents of China, with a focus on populations identified by WHO as being at increased risk for severe influenza and/or a target group for influenza vaccination. This includes, but is not limited to: pregnant women, healthcare workers, poultry workers and other persons with occupational risk for influenza infection, children 6 to 59 months of age, older adults, and those with high risk medical conditions. Results from these activities will also indirectly inform and benefit the US and other world populations.

Collaboration/Partnerships

Activities supported by this NOFO will build upon existing partnerships with local and provincial centers for disease control and ministries of agriculture or other organizations important for pandemic preparedness within China. New and established partnerships with regional/sub-regional ministries of health and agriculture, provincial and municipal health departments, academic institutions, or others to facilitate access and cooperation in meeting research study objectives, will also be supported.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims based on a five (5)-year research project period. The initial application should describe goals for all five years, with an emphasis on the activities for the first year. If awarded, subsequent continuation applications should describe progress towards the long-term goals from the previous year, and emphasize research activities for each subsequent year. 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 develop and implement project performance measures that are based on specific programmatic objectives.

Translation Plan

Applications should include a plan to estimate and report upon the potential translatability and public health impact of the proposed research. Findings should be disseminated to local, regional, and international stakeholders including, but not limited to: the National Health and Family Planning Commission, China; the Ministry of Agriculture in China; and relevant provincial and local health bureaus and centers for disease control. Dissemination of this information will inform and foster review of influenza vaccination and other prevention policies, as well as pandemic preparedness activities. Information on seasonal and novel influenza virus detection should be shared globally with WHO and other partners through the use of a surveillance report or other publication.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $10,000,000

Year 1: $2,000,000

Year 2: $2,000,000

Year 3: $2,000,000

Year 4: $2,000,000

Year 5: $2,000,000

Estimated total funding available for the first year (12-month budget period), including direct and indirect costs: $2,000,000

Estimated total funding available for the entire five (5)-year project period, including direct and indirect costs: $10,000,000

Anticipated Number of Awards: 1

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

The ceiling and floor amounts listed below are for individual awards for the first 12-month budget period.

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

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

Award Floor: $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.

Section III. Eligibility Information

1. Eligible Applicants

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

Additional Eligibility Category:

Other:

Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

2. Foreign Organizations

Foreign Organizations are eligible to apply.

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

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

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

3. Special Eligibility Requirements

Eligibility of this cooperative agreement is limited to the Chinese Center for Disease Control and Prevention, Beijing, China.

4. Justification for Less than Maximum Competition

Eligibility for this NOFO is limited to the Chinese Center for Disease Control and Prevention (China CDC), Beijing, China. China CDC is the only public health research institute in China with advanced capacity to perform the laboratory and epidemiologic studies and analyses needed for the evaluation of Asian influenza A (H7N9) and other seasonal, epidemic and pandemic strains of influenza in China. To effectively address the domestic and global threat posed by new and emerging influenza virus strains in circulation in this part of the world, the research objectives for this study must be carried out in China. China is the only country with Asian influenza A (H7N9), a novel influenza virus with high pandemic potential. China CDC is the only national country institution with sufficient infrastructure to perform the scope of the proposed epidemiologic studies on novel and emerging influenza virus strains in China. As the premier public health institution in China, China CDC is the most appropriate and only national agency qualified to conduct the public health activities specified in the NOFO.

Country Location and Institutional Capacity

- The objectives of this NOFO can only be accomplished if performed in China because China is the only source of A (H7N9), a novel influenza virus with high pandemic potential. Of global concern are the surrounding emerging influenza strains and the pandemic potential posed from genetic evolution of the highly pathogenic avian influenza viruses A (H5N1) and the reassortant virus A (H7N9).
- China CDC maintains partnerships with multiple local and global academic and public health institutions and has collaborated with the US Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD), Influenza Division on influenza disease detection, prevention, and control for over 20 years. China CDC houses one of the world's six World Health Organization (WHO) Collaborating Centers for Influenza and is the WHO Influenza Collaborating Center serving the Western Pacific Region.
- The more than two-decade collaboration between CDC's Influenza Division and China CDC has been invaluable to domestic and global disease control; more than 39 peer-reviewed influenza publications have been produced and have guided influenza policy.
- China CDC has reliable and established systems for sharing global public health information with CDC and the Global Influenza Surveillance and Response System at WHO that are essential for adequate disease surveillance and control.
- China CDC is the national public health agency for China, making it uniquely positioned to perform public health program evaluations and research studies to assess the impact and benefit of influenza vaccination in WHO-identified high risk populations. Results from this work are necessary to effectively inform pandemic risk and national influenza vaccination strategies to reduce morbidity and mortality.

Public Health Surveillance and Laboratory Capacity

- China CDC has well-established public health surveillance systems to identify new human infections from novel influenza viruses and to identify seasonal and epidemic disease. For example, China CDC conducts studies to characterize novel influenza viruses, including influenza A (H5N1) and A (H7N9), in poultry and humans, provides

surveillance among live bird market workers, and gathers information on changes in disease patterns, risk factors and circulating viruses; all capacities critical for the success of the NOFO's objectives.

- China CDC has important and relevant laboratory capacities, including the use of sophisticated genetic next-generation sequencing, and candidate vaccine virus production, to detect and assess the risk of novel influenza viruses in poultry and humans.
- China CDC has, in place, the central, provincial and district-based infrastructure required to immediately engage in the activities listed in this announcement; this should result in more rapid implementation of live-saving interventions.
- China CDC is the key governmental agency that will enable US CDC to execute its global influenza strategy. Specifically, the US CDC, working through its strong partnership with China CDC, will assure the implementation and evaluation of influenza research programs that will result in the prevention and control of influenza in China, the region and the world. For example, the research findings from the current collaboration between CDC and China CDC have contributed to China's policy for influenza vaccines for vulnerable populations and the expansion of influenza vaccine programs among children and older adults.

In summary, the past collaborations between the US CDC Influenza Division and China CDC have established a research coalition and infrastructure that is optimally conducive to performing the studies needed to support applied research and surveillance for better defining the risk of novel and seasonal influenza virus infections in humans and animals, as outlined in the NOFO. Disapproval of this single source justification would erase the benefits derived from the time, effort and funds expended during previous collaborations and would create a gap in available infection control data needed to prevent and control the spread of highly pathogenic avian influenza. Spread of the highly pathogenic avian influenza virus would result in significant morbidity and mortality among US and international populations and global travelers.

5. Responsiveness

Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously-funded research or non-research projects already awarded, regardless of the funding source.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed

annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement,(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

2. Content and Form of Application Submission

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

Duplication of Efforts

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

3. Letter of Intent

Due Date for Letter of Intent: **01/23/2018**

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404- 718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Notices of Funding Opportunities(NOFOs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

Human Subjects Section

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

Other Research Plan Sections

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

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the NOFO. All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.

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

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

• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Please note the new requirement for a data management plan (DMP) to be included as part of the application as described above.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms

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

9. Submission Dates & Times

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

validation and the grantor has confirmed receipt of the application.

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

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

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

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the NOFO (ogstims@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **03/21/2018**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for

release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please
see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

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) 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).

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

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

12. Other Submission Requirements and Information

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

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential

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

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.
See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding _errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm
Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

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

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

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

Significance

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

- How will successful completion of the aims change national, regional, and/or global preparedness to respond to emerging respiratory pathogens with pandemic potential, including novel influenza viruses?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Do the investigators have a successful track record in public health research?
- Do the investigators have demonstrated experience in conducting large clinical or epidemiological studies?
- Are appropriate epidemiologic, laboratory, and biostatistical scientists included among the study investigators?
- Does the investigative team demonstrate proficiency in laboratory testing for influenza?
- Do the investigators demonstrate English proficiency in writing?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- Does the application propose new and unique studies to better understand novel viruses in China?
- Does the application propose studies that will inform global or local policy for the prevention and control of seasonal and novel influenza viruses?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Does the application describe, in detail, the RT-PCR laboratory methods to be used for influenza and other respiratory virus detection and demonstrate competency in the use of these methods?
- Has a plan to demonstrate the quality of the laboratory methods been described in the application?
- Does the application include salient and plausible methods to achieve objectives outlined in specific studies?
- Does the application describe how data will be shared with collaborators from US CDC including both laboratory and epidemiology data and virus for additional laboratory analysis?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the application describe a project that utilizes critical partnerships or collaborations?
- Does the application describe a project that supports key stakeholder involvement throughout the research process?

2. Additional Review Criteria

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

Protections for Human Subjects

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3)

sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.html).
If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

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

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

Investigators responding to this notice of funding opportunity should include a detailed Data Management Plan (DMP) in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. Reviewers will consider whether the DMP includes: the data to be produced in the proposed project; standards to be used for collected or created data; mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights); use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.

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

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html
New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.
Investigators responding to this notice of funding opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation. The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.
The DMP should include, at a minimum, a description of the following:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.
The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.docx

4. Review and Selection Process

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

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

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

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

- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.
In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this notice of funding opportunity.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

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

2. CDC Administrative Requirements

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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. CDC programs must indicate which ARs are relevant to the NOFO. All NOFOs from the Center for Global Health must include AR-35. Recipients must then comply with the ARs listed in the NOFO. Do not include any ARs that do not apply to this NOFO. NOFO Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www. access.gpo.gov/ nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-12: Lobbying Restrictions

AR-14: Accounting System Requirements

AR-22: Research Integrity

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

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

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 - FY 2012 Enacted ;General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR 34: Language Access for Persons with Limited ;English Proficiency ;

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

To view brief descriptions of relevant CDC requirements visit:

http://www.cdc.gov/grants/additionalrequirements/index.html

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must

approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.
This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).
The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- In collaboration with CDC scientists, develop detailed protocols and implementation plans for each proposed study to accomplish the objectives of the research plan;
- Work with CDC scientists to refine study protocols;
- Ensure that all influenza laboratory methods are approved by the Influenza Division, CDC and make all reasonable efforts to adopt CDC protocols when requested by CDC;
- Perform, or arrange to have performed elsewhere: serologic laboratory influenza assays

for influenza antibodies by CDC-approved methods; typing and subtyping of strains; antigenic characterization; sequencing and isolation of viruses as appropriate; and other laboratory assays such as those for cell-mediated immunity and nutritional markers;
- Maintain research data in compliance with internationally accepted safeguards, including compliance with U.S. 45 CFR 46 for human subjects-related data;
- Obtain and subsequently maintain approval of all study protocols by local institutional review boards (IRBs);
- Establish mechanisms to collect epidemiologic data relevant to the project aims, and have clean electronic data available for analysis within three months of collection;
- Specify in research protocols the roles and responsibilities of all investigators, including development and dissemination of reports and manuscripts, prior to initiation of the work;
- Share anonymized data with CDC;
- Work with CDC to analyze and publish data collaboratively, as warranted by contribution;
- Present and submit key studies (or their various components) for publication in peer-reviewed journals within 12 months after completion of each study;
- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access;
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project;
- Working with CDC scientists to obtain OMB-PRA approvals, as needed;
- 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 of 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 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 have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access;
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed;

- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary;
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf .

For applicants that are successfully funded under this NOFO, the recipient agrees that upon award, their application and the summary of reviewers' comments will be shared with the CDC staff who will serve as collaborators on this research project and who provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access, consistent with current HHS/CDC policies.

Additionally, a Scientific Program Officer in the NCHHSTP Extramural Research Program Office (ERPO) will be responsible for the normal scientific and programmatic stewardship of the award as described below:

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

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

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

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

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

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

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

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR)** SF 425 https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the Period of Performance.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the

current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

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

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

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

- Current Budget Period Financial Progress: Status of obligation of current budget period

funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

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

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date. Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://commons.era.nih.gov/commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The recipient's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe

how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

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

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

Scientific/Research Contact

Deborah Loveys, Ph.D.
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8834
Fax: 404-718-8822
Email: dloveys@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

Financial/Grants Management Contact

Steward Nichols
Office of Grant Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2920 Brandy Wine Road, MS E-15

Atlanta, GA 30341

Telephone: 770-488-2788

Fax: 770-488-2688

Email: SHN8@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

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

Public Health Service Act, Sections 301(a) [42 U.S.C. 241(a)] and 307 [42 U.S.C. 242l].