Centers for Disease Control

National Center for Emerging and Zoonotic Infectious Diseases Extramural Research Program Office

Quantifying Contact Rates and Mixing Patterns in Workers in Non-healthcare Work Settings in the United States and Modeling the Effect of Workplace Social Distancing Measures in Reducing Influenza Transmission
RFA-CK-19-002
Application Due Date: 03/19/2019
Quantifying Contact Rates and Mixing Patterns in Workers in Non-healthcare Work Settings in the United States and Modeling the Effect of Workplace Social Distancing Measures in Reducing Influenza Transmission

RFA-CK-19-002

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

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
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<td>Centers for Disease Control</td>
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<tr>
<th>Components of Participating Organizations</th>
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<tr>
<td>National Center for Emerging and Zoonotic Infectious Diseases Extramural Research Program Office (NCEZID ERPO)</td>
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<th>Notice of Funding Opportunity (NOFO) Title</th>
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<td>Quantifying Contact Rates and Mixing Patterns in Workers in Non-healthcare Work Settings in the United States and Modeling the Effect of Workplace Social Distancing Measures in Reducing Influenza Transmission</td>
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<th>Activity Code</th>
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<td>U01 – Research Project - Cooperative Agreements</td>
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<th>Notice of Funding Opportunity Type</th>
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<th>Agency Notice of Funding Opportunity Number</th>
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<th>Assistance Listings (CFDA) Number(s)</th>
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<th>Category of Funding Activity:</th>
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<td>Health</td>
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<tr>
<th>NOFO Purpose</th>
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<tr>
<td>The purpose of this notice of funding opportunity (NOFO) is to: (1) conduct research that describes individual social contact and mixing patterns in workers in non-healthcare work settings in the United States; and (2) assess the feasibility and effectiveness of various workplace social distancing strategies in reducing or slowing the transmission of influenza. The goal is to support the development of innovative workplace prevention and control strategies for reducing or slowing the transmission of pandemic influenza.</td>
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<th>Key Dates</th>
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<td>Publication Date:</td>
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<td>To receive notification of any changes to RFA-CK-19-002, return to the synopsis page of this announcement at <a href="http://www.grants.gov">www.grants.gov</a> and click on the &quot;Send Me Change Notification Emails&quot; link. An email address is needed for this service.</td>
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<tr>
<td>Letter of Intent Due Date:</td>
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<td>01/18/2019</td>
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<td>Application Due Date:</td>
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<td>03/19/2019</td>
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On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications
must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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

Scientific Merit Review: 04/23/2019
Secondary Review: 05/21/2019
Estimated Start Date: 09/01/2019
Expiration Date: 03/20/2019
Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions
**ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED**

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

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 project is to (1) conduct research that describes individual social contact and mixing patterns in workers in non-healthcare work settings in the United States; and (2) assess the feasibility and effectiveness of various workplace social distancing strategies to reduce or slow the transmission of influenza. The goal is to support the development of innovative workplace prevention and control strategies for reducing or slowing the transmission of pandemic influenza.
- **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 four (4)-year project period is $2,500,000. The number of awards is up to two (2). Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $700,000 with individual awards ranging from $250,000 to $350,000 for the first year. The estimated total funding (direct and indirect) for the entire four (4)-year project period is $2,500,000. The project period is anticipated to run from 09/01/2019 to 08/31/2023.
- **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.** See Section III of this announcement for institutions/organizations 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 completing the application package.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Part 2. Full Text

Section I. Funding Opportunity Description
Statutory Authority
Section 317(k)(2) of the Public Health Service Act [42 U.S.C. 247b(k)(2)], as amended.

1. Background and Purpose
About two-thirds of the US civilian non-institutionalized population aged over 16 years participate in the labor force. Workplaces are one of the important venues for transmission of influenza. Droplets and possibly aerosols generated by coughs and sneezes are a major source of influenza transmission. Social contact made in the workplace represent 20% to 25% of all contacts in the community and, on average, 16% (range, 9% to 33%) of influenza transmission occurs in the workplace. In a severe pandemic, the influenza illness attack rate in the workplace can be over 20%.

On April 21, 2017, HHS and CDC released updated pre-pandemic planning guidelines entitled "Community Mitigation Guidelines to Prevent Pandemic Influenza – United States, 2017" (1) (https://www.cdc.gov/mmwr/volumes/66/rr/pdfs/rr6601.pdf). The 2017 guidelines include recommendations on non-pharmaceutical interventions (NPIs) that persons and communities can take to help slow the spread of respiratory virus infections, including seasonal and pandemic influenza viruses. NPIs can be used early during the course of a pandemic, in conjunction with available pharmaceutical interventions (e.g., antiviral medications), to help slow transmission in communities, especially when a vaccine is not yet widely available. Given current vaccine technology, a pandemic vaccine might not be available for up to 6 months. The goals for implementing NPIs early in a pandemic include slowing acceleration of the number of influenza cases in a community, reducing the peak number of cases during the pandemic and the related health care demands on hospitals and infrastructure, and decreasing overall cases and health effects. Categories of NPIs that may be recommended for use during a severe influenza pandemic include personal protective measures (e.g., voluntary home quarantine of exposed household members and use of face masks in community settings when ill) and community measures aimed at increasing social distancing (e.g., temporary school closures and dismissals, postponing or cancelling mass gatherings, and limiting face-to-face contact in workplaces).

Social distancing measures aim to prevent the frequency of face-to-face contact to decrease the risk of person-to-person influenza transmission that occurs through respiratory droplet exposure, which is believed to occur within a contact range of 3 to 6 feet.

Social distancing measures in non-healthcare workplaces can include increased use of teleworking, email and teleconferences; staggered work hours; segregation into small groups; and spacing workers further apart. Access to telework aligns with the recommendation for social distancing in a pandemic. About 24% of employed persons telecommute, but the ability to telecommute varies by occupation (2). Telecommuting rates are substantially higher in management, business, and financial operations (38%) and professional (35%) occupations. It is lower in occupations such as service (11%) and production (6%).

Studies that have assessed the effectiveness of social distancing measures in non-healthcare workplaces on reducing influenza transmission are mostly based on simulation models (3). Input parameters used in simulation models include population characteristics of exposure venues (e.g., workplaces, schools, households), behaviors that represent the frequency of exposure (e.g., rate and duration of contact in workplaces, schools, and households), and disease transmission parameters. However, there is a paucity of empirical studies on contact rates in
workplaces and there are no published studies that provide empirical data on the effect of workplace social distancing interventions on reducing workplace contact rates.

The purpose of this project is to: (1) conduct research that describes individual social contact and mixing patterns in workers in non-healthcare work settings in the United States; and (2) assess the feasibility and effectiveness of various workplace social distancing strategies in reducing or slowing the transmission of influenza. The goal is to support the development of innovative workplace prevention and control strategies for reducing or slowing the transmission of pandemic influenza.

References


Healthy People 2020 and other National Strategic Priorities
This NOFO addresses the “Healthy People 2020” focus area of Immunization and Infectious Diseases. It is in alignment with the goal to prevent disease, disability, and death from infectious diseases, including vaccine-preventable diseases.


Public Health Impact
Community mitigation measures, known also as non-pharmaceutical interventions (NPIs), can be used from the earliest stages of an influenza pandemic, before a vaccine against the new pandemic virus becomes broadly available. Social distancing is one of the community mitigation measures that may be recommended during a severe pandemic. Social distancing can reduce the transmission of pandemic influenza virus by increasing physical distance or reducing the frequency of congregation in community settings, such as workplaces.

The research supported by this NOFO should facilitate development of innovative workplace social distancing strategies for reducing or slowing the transmission of pandemic influenza.

Relevant Work


2. Approach

The award recipient will lead the design and implementation of research that describes individual social contact and mixing patterns and assesses the feasibility and effectiveness of various workplace social distancing strategies in workers from a minimum of four US non-healthcare companies or organizations. The study design should include data collection from workers in one or more of the following occupational settings or occupations: management, business, and financial operations; professional and related occupations. Workplace settings such as healthcare, school, university, prison, and jail should not be included in the research application.

Because large businesses employ more than half of all employees in the United States, preference should be given to collecting social contact and mixing pattern data in large companies (i.e., companies with 500 or more employees) and from companies where workers routinely or periodically wear proximity sensors as part of their normal process, or are willing to wear proximity sensors.

If laboratory testing for influenza is proposed, enrolling companies that have an on-site clinic that is equipped to do diagnostic testing is encouraged.

The application should address the following study parameters and process considerations in the proposed study design, timeline and budget.

- Use of wireless sensor devices, or other novel wearable technologies, to collect data on
social contact and mixing patterns in a minimum of four (4) participating non-healthcare companies or organizations.

- Collection of data on social contact and mixing patterns among workers in at least four non-healthcare companies, including the frequency, duration, type (physical, non-physical) and location of contacts. Since seasonality may influence contact rates and mixing patterns, the potential study period should include all seasons of the year during the chosen study period with the final year (Year 4) of the award dedicated to data analysis, manuscript writing and close-out of the award.
- Collection of data on variables that may be related to contact rates and mixing patterns including, but not limited to, the gender and age of study subjects, access to telework, availability of sick leave and other factors (e.g., day of week, time of day, job type, management level, work group size, work shift, business type, relevant characteristics of the physical environment, season).
- Use of data on social contact and mixing patterns to identify opportunities for targeting workplace social distancing interventions (e.g., reducing congestion in the cafeteria or other locations with high contact rates; focusing on workers with high contact rates).
- Conduct of in-depth interviews and/or focus groups of key management staff from participating companies to assess the feasibility of implementing various workplace social distancing interventions in their companies.
- Use of agent-based models that incorporate the study data on social contact and mixing patterns to assess the effect of implementing various workplace social distancing interventions in reducing or slowing influenza illness attack rates.
- Documentation of the use of any routine disease prevention measures (e.g., seasonal influenza vaccination), as well as any non-pharmaceutical interventions that are implemented during the course of an outbreak of influenza or influenza-like respiratory illness.
- Use of rapid diagnostic tests or RT-PCR (singleplex or multiplex) of nasopharyngeal swabs, if laboratory testing is conducted to ascertain if outbreaks of influenza are observed during the observation period of the study.
- Inclusion of a plan to: a) ensure the security and protection of the identities of the study participants, and b) submit de-identified individual-level study data to the CDC at the end of each budget year.
- It is anticipated that Office of Management and Budget (OMB) review and approval, per the Paperwork Reduction Act (PRA), will be needed prior to initiating data collection. The complete OMB-PRA review and approval process may require 6 to 9 months and should be accounted for in the study design.

Objectives/Outcomes

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

The research questions to be addressed during the course of the study include the following:

1. What is the frequency, duration, type (physical, nonphysical) and location of contact in the workplace?
2. What is the effect of age, gender, access to telework and other factors (e.g., job type,
work group size, time of day, day of week, season) on the frequency, duration and type of contact?
3. For workers who have access to telework, what is the frequency, duration and type of contact with household members on telecommuting days compared to that on non-telecommuting days?
4. What is the feasibility of implementing various workplace social distancing interventions?
5. What is the effect of implementing various workplace social distancing interventions in reducing or slowing influenza illness attack rates?

Target Population
The target population is adult workers in non-healthcare companies or organizations in the United States.

Collaboration/Partnerships
The award recipient should conduct the research project in partnership with non-healthcare companies or organizations to enroll study participants. Letters of support from partner companies or organizations should be included in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Evaluation/Performance Measurement
The application should include measurable goals and aims based on a four (4)-year research project period. The application should include specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application’s project plan, and describe the development and implementation of project performance measures based on specific programmatic objectives.

Translation Plan
The application should include a translation plan that describes how the significant findings resulting from this work may be used to promote, enhance, or advance translation of the research to practice or to inform 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 application should identify which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, the application should describe how the results of this project could be generalized to populations and communities outside of the study. The application should describe how findings from the initial study will be disseminated via manuscripts prepared for publication in relevant scientific, peer-reviewed journals, webinars and presentations at national conferences.

Section II. Award Information
Funding Instrument Type: Cooperative Agreement
A support mechanism used when there will be substantial Federal scientific or
programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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

**Estimated Total Funding:** $2,500,000

**Estimated Total Annual Budget Period Funding:**
- Year 1: $700,000.
- Year 2: $700,000.
- Year 3: $700,000.
- Year 4: $400,000.

**Estimated total funding available for first year (first 12 months), including direct and indirect costs:** $700,000.

**Estimated total funding available for entire project period, including direct and indirect costs:** $2,500,000

**Anticipated Number of Awards:** 2

Ceiling and Floor amounts listed below are per award for the first 12-month budget period only.

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

**Award Ceiling:** $350,000 Per Budget Period

**Award Floor:** $250,000 Per Budget Period

**Total Period of Performance Length:** 4 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 ([http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf](http://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.

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**Section III. Eligibility Information**

**1. Eligible Applicants**

Eligibility Category: State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments
(Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations
(Other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

Additional Eligibility Category:

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

Federally Funded Research and Development Centers (FFRDCs):
FFRDCs are operated, managed, and/or administered by a university or
A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://dap.dau.mil/acquipedia/Pages/ArticleDetails.aspx?aid=5e3079b8-44f2-43df-a0e7-9f379e8c48ed

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

Additional Information on Eligibility:

Non-profit Private Institutions of Higher Education are eligible to apply.

For-profit institutions are not eligible to apply.

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Non-profit Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously-funded research already awarded under other awards.
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%20for%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/.
- 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 Principle Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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

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

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

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

· E-mail: http://grants.nih.gov/support/index.html
2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide [http://grants.nih.gov/grants/how-to-apply-application-guide.htm] and here: [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.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 package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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

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

Please include all of the eight (8) mandatory forms listed below in the application package:

**Mandatory**

1. SF424(R&R)[V2.0];
2. PHS 398 Cover Page Supplement [V4.0];
3. Research and Related Other Project Information [V1.4];
4. Project/Performance Site Location(s) [V2.0];
5. Research and Related Senior/Key Person Profile (Expanded) [V2.0];
6. Research and Related Budget [V1.4];
7. PHS 398 Research Plan [V4.0];
8. PHS Human Subjects and Clinical Trials Information [V1.0].

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

**Optional**

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

3. Letter of Intent

Due Date for Letter of Intent: 01/18/2019

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

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

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

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
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. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component
The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and 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 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf](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](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

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

**Please note:** According to the Additional Requirement-25 (AR-25) ([https://www.cdc.gov/grants/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/additionalrequirements/ar-25.html)), investigators who 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 as follows:

The DMP must describe how investigators will make data readily available. Investigators 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. A Data Management Plan (DMP) is required for each collection of public health data proposed. The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include **the following five elements:**

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

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**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.

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**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 30 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](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](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 strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.

Organizations must submit applications using the ASSIST web-based application preparation and submission process.

ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.

**Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.**

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


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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:

Toll-free: 1-866-504-9552; Phone: 301-402-7469


Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:

Toll-free: 1-800-518-4726

[https://www.grants.gov/web/grants/support.html](https://www.grants.gov/web/grants/support.html)
support@grants.gov

Hours: 24 hours a day, 7 days a week (closed on federal holidays)
If the applicant encounters problems that prevent the ability to submit an application which
cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact
CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov
for guidance at least 3 calendar days before the deadline date. Therefore, it is important that
applicants complete the application submission process well in advance of the due date time.

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

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

1. Track submission and verify the submission status (tracking should be done initially
   regardless of rejection or success).
   a. If the status states "rejected", do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.
   a. If the deadline has passed, he/she should email the Grants Management contact listed in
      the Agency Contacts section of this announcement and ogstims@cdc.gov explaining why
      the submission failed.
   b. If there is time before the deadline, correct the problem(s) and resubmit as soon as
      possible.

Due Date for Applications: 03/19/2019

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 Protective 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.

Additional Funding Restrictions:

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

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

3) 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).

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

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

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

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### 12. Other Submission Requirements and Information

#### Risk Assessment Questionnaire Requirement

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

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

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

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**Duplication of Efforts**

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

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

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

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. PAPER APPLICATIONS WILL NOT BE ACCEPTED.

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm? id=11144).

Important reminders:
All 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:


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](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?
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?

Have the investigators published scientific articles in peer-reviewed journals on social contact and mixing patterns and on using agent-based models to simulate disease transmission?

Innovation

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

Approach

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

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

Does the application include plans to modify an existing agent-based model on influenza transmission in order to assess the effect of implementing various workplace social distancing interventions in reducing or slowing influenza illness attack rates? If so, does the application include references to publications based on the existing agent-based model?

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 partnering with companies where workers routinely or periodically wear proximity sensors as part of their normal work process, or are willing to wear proximity sensors? If so, is this information documented in Letters of Support from CEOs?

Does the application package include Letters of Support from partner organizations?

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

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

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

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

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

**Vertebrate Animals**
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following 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.


### 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.

**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](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](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 sub-awards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

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

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

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**4. Review and Selection Process**

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

As part of the scientific peer review, all applications:

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

- Will receive a written critique.

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

- Geographic diversity by region. Regions are defined as consisting of the following states, territories, districts: Region 1 - CT, MA, ME, NH, RI, VT; Region 2 - NJ, NY, Puerto Rico, US Virgin Islands; Region 3 - DE, MD, PA, VA, WV, District of Columbia (DC); Region 4 - AL, FL, GA, KY, MS, NC, SC, TN; Region 5 - IL, IN, MI, MN, OH, WI; Region 6 - AR, LA, NM, OK, TX; Region 7 - IA, KS, MO, NE; Region 8 - CO, MT, ND, SD, UT, WY; Region 9 - AZ, CA, HI, NV, American Samoa, Guam, US Trust Territories of the Pacific Islands; Region 10 – AK, ID, OR, WA. See: http://www.hhs.gov/about/agencies/iea/regional-offices/index.html

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 grantee’s business official.

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

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-8: Public Health System Reporting Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-20: Conference Support
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-23: Compliance with 45 C.F.R. Part 87
AR-25: Policy on Public Health Research and Non-research Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-27: Conference Disclaimer and Use of Logos
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR-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
AR-36: ; Certificates of Confidentiality

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

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

3. Additional Policy Requirements
The following are additional policy requirements relevant to this NOFO:

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

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

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

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

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

**Language Access for Persons with Limited English Proficiency** Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person’s race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take 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. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will
work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at [http://www.phe.gov/s3/dualuse](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](https://www.cdc.gov/grants/additionalrequirements/ar-25.html) outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

### 4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism
The PD(s)/PI(s) will have the primary responsibility for:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Providing de-identified study data to CDC at the end of the funding period.
- 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
Areas of Joint Responsibility:

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

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

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

5. Reporting

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act),
includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

1. Information on executive compensation when not already reported through the SAM Registration.
2. Similar information on all sub-awards/subcontracts/consortia over $25,000.

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

Additional information regarding the use of eRA Commons may be found at the following website:

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 grantee’s final report should include:

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

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

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

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

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

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 Standard Time

Scientific/Research Contact
Deborah Loveys, Ph.D.
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 Rd, MS E-60
Atlanta GA 30333
Telephone: 404-718-8834
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
Email: GAnderson@cdc.gov
Section VIII. Other Information

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

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

Section 317(k)(2) of the Public Health Service Act [42 U.S.C. 247b(k)(2)], as amended