Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention (CDC)

The policies, guidelines, terms, and conditions of the HHS Centers for Disease Control and Prevention (CDC) stated in this notice of funding opportunity (NOFO) might differ from those used by the HHS National Institutes of Health (NIH). If written guidance for completing this application is not available on the CDC website, then CDC will direct applicants elsewhere for that information.

Components of Participating Organizations

National Institute for Occupational Safety and Health (NIOSH)

Funding Opportunity Title

World Trade Center Health Program Mentored Research Scientist Career Development Award (K01)

Activity Code

K01 Research Scientist Development Award - Research & Training

Announcement Type

New

Related Notices

None

Notice of Funding Opportunity (NOFO) Number

RFA-OH-24-004

Companion Notice of Funding Opportunity

None

Number of Applications

Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct. See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.262

Funding Opportunity Purpose

The purpose of the National Institute for Occupational Safety and Health (NIOSH) and World Trade Center (WTC) Health Program Mentored Research Scientist Career Development Award (K01) is to provide support and 75% “protected time” (up to 3 years) for an intensive, supervised (mentored) career development experience in WTC-related health research. This can facilitate the transition of junior research scientists from the mentored to the independent stages of their careers in WTC-related health research. By providing support for the critical transition period between postdoctoral training and independent U01 or R01 funding for investigators, NIOSH/WTC Health Program hopes to foster the careers of these investigators, who are vital for the future excellence of WTC-related health research endeavors.

Applicants must justify the need for a period of mentored research experience and convincingly describe how the proposed period of support will substantially enhance their careers as independent investigators. Applicants must also concisely describe the issues related to diagnostic or treatment uncertainty addressed in their proposal. Applicants should clearly articulate the anticipated impacts of the proposed research, both during the project period and beyond.

The NIOSH/WTC Health Program supports K01 grants to help ensure the availability of an adequate number and diversity of highly trained scientists and educators to address issues related to diagnostic or treatment uncertainty with respect to individuals receiving monitoring and/or treatment under subtitle B of the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328).

WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the population targeted for the research project. Research funded by the WTC Health Program is primarily intended for the benefit of the 9/11-exposed population. It is not required that project findings be generalizable to other populations.

NIOSH is soliciting Mentored Research Scientist Career Development research projects within the following six major areas of clinical research interest: Implementation Research, Health Services Research, Health Equity Research, Treatment Research, Prevention Research, and Quality of Life Research.

The WTC Health Program Research webpage provides comprehensive information and tools

for researchers. The research agenda, publication library, and other resources, including the Funding Dashboard, can also be found there (e.g., awarded project details such as publications, topics, populations, funding awarded, and the principal investigators and their institutions).

Key Dates

Posted Date

August 17, 2023

Open Date (Earliest Submission Date)

November 1, 2023

Letter of Intent Due Date(s)

November 1, 2023 (LOI recommended but not required)

Application Due Date(s)

December 5, 2023

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** on the listed application due date.

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

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service Desk via https://www.era.nih.gov/need-help.

E-mail: commons@od.nih.gov

Phone: 301-402-7469 or (toll-free) 1-866-504-9552

Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Note: HHS/CDC grant submission procedures do not provide a 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).

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

March 2024

Advisory Council Review

April 2024

Earliest Start Date

July 1, 2024

Expiration Date

January 4, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

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

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.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Statutory Authority

The World Trade Center Health Program is authorized under Section 301 of the Public Health Service Act as amended (42 U.S.C. 241) and the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328); codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. §§ 300mm – 300mm–62. The authority for this specific research is found in Section 3341 of the Zadroga Act, as amended (42 U.S.C. §§ 300mm–51).

Background

The World Trade Center (WTC) Health Program is administered by the National Institute for Occupational Safety and Health (NIOSH). Program information is available at the WTC Health Program website. The James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111–347 (hereafter referred to as “the Zadroga Act”) was signed by President Obama on January 2, 2011, and was re-authorized on December 18, 2015 (the

Consolidated Appropriations Act, 2016, Public Law 114–113), and further amended by Public Laws 116–59 and 117-328. The Zadroga Act established monitoring and treatment activities for responders and survivors of the September 11, 2001, terrorist attacks and requires the establishment (under Subtitle C) of a research program on health conditions resulting from the attacks.

The Zadroga Act lists the following broad research areas (42 U.S.C. § 300mm–51):

- Physical and mental health conditions that may be related to the September 11, 2001, terrorist attacks;
- Diagnosing WTC-related health conditions for which there has been diagnostic uncertainty; and
- Treating WTC-related health conditions for which there has been treatment uncertainty.

Research conducted under the Zadroga Act includes epidemiologic and other research studies on WTC-related health conditions or emerging conditions among (1) WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors under treatment and individuals who were exposed within a geographic area related to the September 11, 2001, terrorist attacks in a manner similar to the exposure within such geographic area experienced by individuals meeting the eligibility criteria under section 3311(a)(2) or 3321(a)(1)(B); and (2) sampled populations outside the New York City disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

The Zadroga Act established the requirement for a WTC Health Program Scientific/Technical Advisory Committee and states that the WTC Program Administrator shall consult with the committee in carrying out research activities related to the September 11, 2001, terrorist attacks.

Purpose

The purpose of the NIOSH and WTC Health Program Mentored Research Scientist Career Development Award (K01) is to provide support and 75% “protected time” (up to 3 years) for an intensive, supervised (mentored) career development experience in WTC-related health research. This can facilitate the transition of junior research scientists from the mentored to the independent stages of their careers in WTC-related health research. By providing support for the critical transition period between postdoctoral training and independent U01 or R01 funding for investigators, NIOSH/WTC Health Program hopes to foster the careers of these investigators, who are vital for the future excellence of WTC-related health research endeavors.

Applicants must justify the need for a period of mentored research experience and convincingly describe how the proposed period of support will substantially enhance their careers as independent investigators. Applicants must also concisely describe the issues related to diagnostic or treatment uncertainty addressed in their proposal. Applicants

should clearly articulate the anticipated impacts of the proposed research, both during the project period and beyond.

The NIOSH/WTC Health Program supports K01 grants to help ensure the availability of an adequate number and diversity of highly trained scientists and educators to address issues related to diagnostic or treatment uncertainty with respect to individuals receiving monitoring and/or treatment under subtitle B of the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328).

WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the population targeted for the research project.

Research funded by the WTC Health Program is primarily intended for the benefit of the 9/11-exposed population. It is not required that project findings be generalizable to other populations.

Major areas of research interest

NIOSH is soliciting Mentored Research Scientist Career Development research projects (K01) within the following six areas of clinical research.

Implementation Research: Projects that study the processes whereby WTC Health Program research outputs are disseminated, adopted, implemented, sustained, and scaled up equitably in real-world settings for affected populations.

Health Services Research: Projects that examine how people get access to health care and care management services, how much care costs, and what happens to patients as a result of this care. Research projects in this area have the potential to identify improved methods/procedures to organize, manage, finance, and deliver health care.

Health Equity Research: Projects that identify/develop methods to systematically determine whether there are unique vulnerabilities and health disparities among individuals exposed to the 9/11 attacks and aftermath or assess distributions of health outcomes among populations and subgroups. Vulnerable groups include but are not limited to, women, minorities, foreign-born individuals, and individuals of all ages, with appropriate representation of older adults and individuals exposed to the WTC disaster prior to 18 years of age.

Treatment Research: Projects that evaluate/identify improved treatment interventions/methods (e.g., medication, psychotherapy, dietary/nutritional, care management and coordination etc.) or promote the development of new or novel treatment approaches, e.g. telemedicine.

Prevention Research: Projects that identify/evaluate new methods and interventions (e.g., medicine(s), psychotherapy, vaccines, nutrition, or lifestyle changes) that prevent or

mitigate the development or reoccurrence of various diseases/disorders.

Quality of Life Research: Projects that identify, develop, or evaluate, methods/interventions that improve comfort and the quality of life for individuals with a chronic illness or multimorbidity.

Relevant focus areas include, but are not limited to:

- nutrition and diet,
- sleep quality/hygiene,
- stress management and positive psychology,
- physical activity,
- social connectedness,
- avoidance of risky substances, and
- optimization of medication usage and reduction in polypharmacy.

Relevant issues/focus areas related to the following outcomes:

- Respiratory diseases,
- Cancer (including prevention/detection/diagnosis of pre-malignant changes) and palliative care,
- Cardiovascular disease,
- Psychiatric conditions such as post-traumatic stress, anxiety and depressive disorders,
- Cognitive reserve, resilience, or decline, and
- Healthy aging.

Health Equity: Project proposals should include discussions describing how research questions, data collection methods and analysis, and dissemination of results will be inclusive of the diversity in the WTC populations, especially those from historically underrepresented groups including women, minorities, foreign-born individuals, and individuals of all ages, including appropriate representation of older adults and individuals exposed to the WTC disaster prior to 18 years of age.

Applications should clearly state:

- how the design, content, format and dissemination of outreach efforts will be tailored to the needs of WTC populations from diverse backgrounds;
- how cultural competence of research and linguistically appropriate dissemination of findings and solutions will be ensured; and
- how historically underrepresented groups can be included in research projects, e.g., though participation on advisory boards, as researchers/staff, and though partnerships.

The WTC Health Program Research webpage provides comprehensive information and tools for researchers. The research agenda, publication library, and other resources, including the Funding Dashboard, can also be found there (e.g., awarded project details such as publications, topics, populations, funding awarded, and the principal investigators and their institutions).

Objectives

The overall objective of this announcement is to solicit meritorious and scientifically rigorous research applications that will help:

- improve diagnosis and treatment activities of the WTC Health Program;
- expand knowledge about health effects related to the September 11, 2001, terrorist attacks;
- answer critical questions about physical and mental health conditions related to the September 11, 2001, terrorist attacks; and
- apply lessons learned from 9/11 to improve response to future disasters.

Clinical trials are not required. A candidate may propose 1) to gain research experience in a clinical trial led by a mentor or co-mentor, or 2) to serve as the lead investigator of an independent clinical trial, a clinical trial feasibility study, or a separate ancillary clinical trial, as part of their research and career development.

Researchers are encouraged to review WTC Health Program funded projects and publications by visiting the Program Research webpage to assist with an assessment of research gaps and needs.

Healthy People 2030 and other National Strategic Priorities

The WTC research program funded by this NOFO will contribute to the CDC strategic goal, in alignment with an HHS strategic goal and objectives found in Healthy People 2030, to increase the number of communities that protect and promote health and safety and prevent illness and injury to improve the safety, quality, affordability, and accessibility of health care.

Public Health Impact

A growing body of evidence suggests that significant health conditions have emerged that are associated with the disaster, particularly for those exposed during the collapse of the towers and those who participated substantially in rescue, recovery, and clean-up operations.

Research to be conducted under the Zadroga Act includes epidemiologic and other research studies on WTC-related health conditions or emerging conditions (1) among enrolled WTC responders and certified-eligible WTC survivors under treatment and individuals who were exposed within a geographic area related to the September 11, 2001, terrorist attacks in a manner similar to the exposure within such geographic area experienced by individuals meeting the eligibility criteria under section 3311(a)(2) or 3321(a)(1)(B); and (2) in sampled populations outside the New York City disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

Scientific research may inform health care professionals and allow earlier diagnoses of WTC conditions, which may lead to more effective treatment. However, scientifically identifying the causes of health problems or conditions is typically very difficult. While it is often not possible to determine the specific cause of an individual's illness or condition, it is critical to promote scientifically rigorous studies and reviews of potential health problems or risk factors among the affected population.

Research funded by the WTC Health Program is primarily intended for the benefit of the 9/11-exposed population. It is not required that project findings be generalizable to other populations.

The WTC Health Program Research webpage provides comprehensive information and tools for researchers. The research agenda, publication library, and other resources, including the Funding Dashboard, can also be found there (e.g., awarded project details such as publications, topics, populations, funding awarded, and the principal investigators and their institutions).

Relevant Work

Information about current and completed NIOSH-funded research studies pertaining to the World Trade Center can be found on the WTC Health Program Research webpage (including two publications from the WTC Health Program: First Decade of Research and a Workshop on Cognitive Aging and Impairment in the 9/11-Exposed Population). The WTC Health Registry's annual reports, prepared for enrollees and the public, include information on its key activities and accomplishments, and details on recent findings about the health consequences of 9/11.

Note: Interested applicants are strongly encouraged to visit the WTC Health Program Research webpage for additional information.

Target Population

The target population for research funded under this NOFO are individuals exposed to the September 11, 2001, terrorist attacks, including responders and community members (also referred to as survivors).

Responder cohorts or populations include:

- local responders (FDNY and others) who were exposed and (a) still live in the NYC area or (b) have since moved away from the NYC area; and
- responders who came from outside the NYC area to assist with the response and subsequently returned to their respective home areas.

Screening-eligible and certified-eligible WTC survivors (adults and children) include individuals who lived, worked, went to school, or attended child or adult day care in the New York City (NYC) Disaster Area, as defined in 42 CFR 88.1, on September 11, 2001, or in the following days, weeks, or months and those otherwise meeting the eligibility criteria in 42 CFR 88.7 or 88.8.

Additionally, proposed research can include sampled populations outside the NYC disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

Collaboration/Partnerships

Interdisciplinary and transdisciplinary collaborations that share expertise are essential to advance WTC Health Program efforts to 1) evaluate linkages between WTC exposures and uncommon health conditions, 2) improve diagnostic and treatment outcomes, and 3) support activities to address emerging WTC Health Program health and well-being priorities.

Ancillary Studies/Secondary Analysis of Existing Data

Applicants considering projects that depend on interaction or collaboration with the Data Centers, or the 9/11 Health Registry associated with the WTC Health Program ("Data Center and WTC Health Registry Contacts", below) must coordinate in advance with the respective Directors or Administrators of the Data Centers to ensure access to data and/or availability of adequate numbers of potential participants are feasible to conduct the proposed research. Documentation of the study recruitment plan and agreement on this coordination must be included in the application, along with any budgetary needs for the coordination activities, by providing both a letter from the investigator to the Data Center/Health Registry/WTC Health Program and a response letter from the Data Center/Health Registry/WTC Health Program to the investigator.

Data Center and WTC Health Registry Contacts

Fire Department of New York

Medical Director – Dr. David Prezant, 718-999-2696, David.Prezant@fdny.nyc.gov

Administrative Director – Ms. Jessica Weakley, 718-999-0412, Jessica.Weakley@fdny.nyc.gov

Associate Director, WTC FDNY Data Center – Dr. Rachel Zeig-Owens, 718-403-4416, Rachel.Zeig-Owens@fdny.nyc.gov

Icahn School of Medicine at Mount Sinai

Director – Dr. Andrew C. Todd, 212-824-7053, Andrew.Todd@mssm.edu

Data Requests – Mr. Christopher R. Dasaro, 332-323-2806, Christopher.Dasaro@mssm.edu

NYC Health and Hospitals Corporation

Medical Director – Dr. Joan Reibman, 212-263-6479, Joan.Reibman@nychhc.org

Executive Director – Mr. Scott VanOrden, 646-458-2711, Scott.VanOrden@nychhc.org

Data Center Director – Ms. Michelle Hyde, 212-788-0949, Michelle.Hyde@nychhc.org

WTC Health Registry

Public Affairs Manager – Paul Gambino, 718-786-4481, pgambino1@health.nyc.gov

Evaluation/Performance Measurement

Evaluations provide information for management and improve program effectiveness. The CDC document Framework for Program Evaluation can be helpful.

Effective program evaluation is a systematic way to improve and account for public health actions by involving procedures that are useful, feasible, ethical, and accurate. Understanding and applying the elements of this framework for research projects may enhance planning effective public health strategies, improving existing programs including evidence-based activities, and demonstrating beneficial results and impact of federal funding.

Translation Plan

When relevant to the goals of the research project, applicants should describe briefly how the findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. See A Way Forward: The Translational Impacts of World Trade Center Health Program Research.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Note: Applicants may propose to gain experience in a clinical trial led by a mentor/co-mentor as part of their research career development.

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

Estimated total funding (direct and indirect) available for this program is expected to be $5.2M; and assumes a 3-year period of performance.

Anticipated number of awards is 6 to 10.

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

Award Budget

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period may not exceed 3 years.

Other Award Budget Information

Salary

CDC/NIOSH/WTC Health Program will contribute up to $100,000 per year toward the salary and fringe benefits of the career award recipient. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide.

In addition, the candidate may derive additional compensation for effort associated with other Federal sources or awards provided the total salary derived from all Federal sources does not exceed the maximum legislated salary rate and the total percent effort does not exceed 100%. See also NOT-OD-17-094.

Other Program-Related Expenses

CDC/NIOSH/WTC Health Program will contribute up to $60,000 per year toward the research development costs of the award recipient, which must be justified and consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities. These funds may be used for the following expenses: (a) tuition and fees related to career development; (b) research-related expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time.

Salary for mentors, secretarial and administrative assistants, etc. is not allowed.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at

8% of modified total direct costs.

HHS/CDC grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made in response to this NOFO.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or 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
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

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

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- 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 consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDCs 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://gov.ecfr.io/cgi-bin/searchECFR.

Foreign Institutions
Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *HHS Grants Policy Statement*, **are not** allowed.

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

Responsiveness
Applications that exceed the 3-year period of performance limit, the $100,000 limit per year for salary and fringe benefits, $60,000 limit per year for research support, or 8% limit on indirect costs (also known as Facilities & Administrative [F&A] Costs) will be considered non-responsive and will not proceed to peer review. In these cases, CDC/NIOSH will notify the applicant and request that the application be withdrawn.

The Candidate Information and Goals for Career Development and Research Strategy (for both attachments combined) are limited to **12** pages. The page limit includes all text, tables, graphs, figures, diagrams, and charts in this component.

Upon receipt, applications will be evaluated for completeness by NIH/CSR and CDC/NIOSH. CDC/NIOSH will screen all applications for responsiveness. Incomplete or non-responsive applications will not be reviewed. Applicants will be requested to withdraw non-responsive applications.

Note to Applicants
You must specify the **WTC Subpopulation(s) under study** (see Section I. Target Population for descriptions) or a combination of these populations. If you propose to study

a combination of these populations, you must clearly state the percentages of each population.

You must also include the **Primary Diseases/Conditions** (e.g., **respiratory disease**, **adult mental health**, **cancer**, **children's research** or **emerging conditions**) that you propose to study, followed by a brief description.

The **WTC Subpopulation(s) under study** and **Primary Diseases/Conditions** must be included as one attachment titled "**Study Information**" in the "12. Other Attachments" section of the "R&R Other Project Information" component of the application. Please note there are other requirements specific to this announcement that must be included in this section of your application: **Project Dissemination Plan** and **Project Evaluation Plan** (see Section V, Additional Review Considerations for information), as well as **CDC Risk Questionnaire** with supporting documentation and **Duplication of Efforts** (see Section IV, Other Submission Requirements and Information for instructions).

Applicants who plan to collect public health data must submit a **Data Management Plan (DMP)** in the Resource Sharing section of the PHS 398 Career Development Award Supplemental Component of the application. A DMP is required for each collection of public health data proposed. CDC OMB-approved templates may be used (e.g., NCCDPHP template). See Section IV, Content and Form of Application Submission and Section V, Additional Review Considerations for information.

The NIOSH Secondary Review Committee (SRC) may categorize and prioritize projects by WTC subpopulation(s) and relevant diseases/conditions based on program needs.

WTC Health Program Reference Documents

The WTC Health Program Research Publication Library

A regularly updated comprehensive listing of 9/11 health research publications from 2001 to present. Publications can be searched by study population, WTC cohort (responders, survivors, both), year of publication, outcome studied (WTC covered and non-covered conditions), and year published.

The WTC Research Grant Project Information Dashboard

The funding dashboard includes all research projects awarded since 2011 (the year that the Zadroga 9/11 Health and Compensation Act was signed into law). Project-specific information includes research institution, Principal Investigator, year awarded, and topic area (respiratory disease, mental health, cancer, cardiovascular disease, emerging conditions, and WTC youth).

Note: Interested applicants are strongly encouraged to review the WTC Health Program Research webpage for more information.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

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

- System for Award Management (SAM)– Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active SAM registration in order to complete the Grants.gov registration. All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs))

must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires

that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission; therefore the applicant organization must ensure that their Grants.gov AOR credentials are active. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

All PD(s)/PI(s) must be registered with ORCID. The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help.

Universal Identifier Requirements and System for Award Management (SAM)
All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its UEI number to the recipient organization.

Eligible Individuals (Program Director/Principal Investigator)
Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with their mentor and organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for HHS/CDC support. **Multiple PDs/PIs are not allowed.**

By the time of award, the individual must be a citizen or a non-citizen national of the

United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

Current and former PDs/PIs on CDC or NIH research project (R01, U01), program project (P01), center grants (P50), other major individual career development awards (e.g., DP5, K01, K07, K08, K22, K23, K25, K76, K99/R00), or Project Leads of program project (P01) or center grants (P50) or the equivalent are not eligible.

Current and former PDs/PIs of a CDC or NIH Small Grant (R03), Exploratory/Developmental Grants (R21/R33), Planning Grant (R34/U34), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible, as do PD/PIs of Transition Scholar (K38) awards and individuals appointed to institutional K programs (K12, KL2).

Candidates for the K01 award must have a research or health-professional doctoral degree.

This funding opportunity may support individuals who propose to train in a new field or individuals who have had a hiatus in their research career because of illness or pressing family circumstances.

NOTE: The CDC does not make awards to individuals directly.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct, and each is from a different candidate. As defined in the HHS Grants Policy Statement, applications received in response to the same NOFO generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. The CDC/NIOSH 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.

The CDC/NIOSH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application. An individual may not have two or more competing CDC career development applications pending review concurrently. In addition, CDC/NIOSH will not accept:

A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications).

Candidates may submit research project grant (RPG) applications concurrently with the K application. However, any concurrent RPG application may not have substantial scientific and/or budgetary overlap with the career award application. K award recipients are encouraged to obtain funding from CDC or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement, or as project leader on a competing multi-project award as described in NOT-OD-08-065. Currently mentored K award recipients in the last two years of their support period are permitted to reduce the level of effort required for the K award and replace that effort with effort on a CDC research grant or subproject provided they remain in a mentored situation.

Level of Effort

At the time of award, the candidate must have a “full-time” appointment at the applicant institution. Candidates are required to commit a minimum of nine person months of effort (i.e., 75% of full-time professional effort) to their program of career development. Candidates may engage in other duties as part of the professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full time requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

After the receipt of the award, adjustments to the required level of effort may be made in certain circumstances. See NOT-OD-18-156. CDC will not reduce full research costs for other budget categories (i.e., Other Personnel, Equipment, Travel, Participant/Trainee Support Costs, Other Direct Costs) approved under the award during the period of reduced effort or part-time appointment, and may extend the award with appropriate justification.

Mentor(s)

Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the area of the proposed research and be committed both to the career development of the candidate and to the direct supervision of the candidate’s research. The mentor must document the availability of sufficient research support and facilities. Candidates are encouraged to identify more than one mentor, i.e., a mentoring team, if this is deemed advantageous for providing expert advice in all aspects of the

research career development program. In such cases, one individual must be identified as the primary mentor who will coordinate the candidate's research. The candidate must work with the mentor(s) in preparing the application. The mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage. Where feasible, the recruitment of women, individuals from diverse racial and ethnic groups, and individuals with disabilities as potential mentors is encouraged, given their ability to serve as role models.

For applicants proposing a clinical trial, ancillary or feasibility study, the mentor(s) or mentoring team must demonstrate appropriate expertise, experience, and ability to guide the candidate in the organization, management and implementation of the proposed research and clinical trial.

Institutional Environment

The applicant institution must have a strong, well-established record of research and career development activities and faculty qualified to serve as mentors in biomedical, behavioral, or clinical research.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system (S2S) solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

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

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

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

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.

Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-H application packages for due dates on or after January 25, 2023. Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide, except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 Application Guide to ensure you complete all appropriate "optional" components.

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

Letter of Intent

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

The letter of intent should be sent to:

Laurel Garrison, MPH
Scientific Review Officer
Office of Extramural Programs (OEP)
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Telephone: 513-533-8324
Email: LEE5@cdc.gov

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits must be followed.

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

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

Applicants must use FORMS-H application packages for due dates on or after January 25, 2023. Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

Instructions for Application Submission
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. The following section supplements the instructions found in the SF 424 (R&R) Application Guide and should be used for preparing an application to this NOFO.

Required Components for this NOFO

SF424(R&R)
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Other Project Information
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

For this NOFO, the following items should be included as attachments in the "12. Other Attachments" section of the "R&R Other Project Information" form of the application. When uploading supporting documentation into this application package, clearly label each item for easy identification of the type of documentation.

- **Study Information** as one attachment, which must include the **WTC Subpopulation(s) under study** and **Primary Diseases/Conditions** (see Section III, Note to Applicants for information).
- **Project Dissemination Plan** (see Section V, Additional Review Considerations for information)
- **Project Evaluation Plan** (see Section V, Additional Review Considerations for information)
- **CDC Risk Questionnaire** with supporting documentation (see Section IV, Other Submission Requirements and Information for instructions)

- **Duplication of Efforts** (see Section IV, Other Submission Requirements and Information for instructions). Write 'None' if no overlap.

Project/Performance Site Location(s)
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Senior/Key Person Profile (Expanded)
All instructions in the SF424 (R&R) Application Guide must be followed.

IMPORTANT REMINDER: The personal profile associated with the eRA Commons username entered in the Credential field for the PD/PI (candidate) must include an ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help.

R&R Budget
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

For this NOFO, CDC/NIOSH requires a detailed budget information for the initial budget year and a budget for each consecutive year of support.

WTC Health Program Research Meetings

Applicants should anticipate and budget accordingly to allow time to attend and present study findings at the required 2-day meeting for WTC Health Program research recipients. The meetings are held bi-annually in New York City (NYC) and may alternate between webinars and in-person meetings.

PHS 398 Career Development Award Supplemental
The PHS 398 Career Development Award Supplemental Form is comprised of the following sections:

Introduction (for Resubmission applications ONLY; Revision applications are not allowed)

Candidate Section

Research Plan Section

Other Candidate Information Section

Mentor, Co-Mentor, Consultant, Collaborators Section

Environment and Institutional Commitment to Candidate Section

Other Research Plan Sections

Appendix

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Candidate Section
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional

instructions:

Candidate Information and Goals for Career Development

Candidate's Background

- Describe the candidate's commitment to a health-related research career. Describe all the candidate's professional responsibilities in the recipient institution and elsewhere and describe their relationship to the proposed activities on the career award.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in their research career, including any publications, prior research interests and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator. Usually this is evident from publications, prior research interests and experience, and reference letters.
- For applicants proposing a clinical trial, ancillary or feasibility study: if applicable, describe the candidate's ability to organize, manage, and implement the proposed clinical trial, feasibility or ancillary clinical trial.
- For applicants proposing a clinical trial, ancillary or feasibility study: if applicable, describe the candidate's prior efforts, interests and experience in clinical trials research.

Career Goals and Objectives

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) that justifies the need for further career development to become an independent investigator.
- For applicants proposing a clinical trial, ancillary or feasibility study: the candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects and clinical trials.

Candidate's Plan for Career Development During Award Period

- The candidate and the mentor(s) are jointly responsible for the preparation of the career development plan. A career development timeline is often helpful.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals.
- Describe the professional responsibilities/activities including other research projects beyond the minimum required 9 person months (75% full-time professional effort) commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Research Plan Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy

- A sound research project that is consistent with the candidate's level of research development and objectives of their career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's

proposed research plan.
- If the applicant is proposing to gain experience in a clinical trial, ancillary study to a clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial.
- Applicants proposing a clinical trial, ancillary or feasibility study should describe the planned analyses and statistical approach and how the expected analytical approach is suited to the available resources, proposed study design, scope of the project, and methods used to assign trial participants and deliver interventions.
- If proposing an ancillary clinical trial, provide a brief description of its relationship to the larger clinical trial.
- If proposing a feasibility study, to begin to address a clinical question, provide justification why this is warranted and how it will contribute to the overall goals of the research project including planning and preliminary data for future, larger scale clinical trials.
- Describe the proposed timelines for the proposed clinical trial, feasibility study or ancillary clinical trial, including any potential challenges and solutions (e.g., enrollment shortfalls or inability to attribute causal inference to the results of an intervention when performing a small feasibility study).
- Describe how the proposed clinical trial or ancillary clinical trial will test the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy (this would not apply to a feasibility study).

Training in the Responsible Conduct of Research

- All applications must include a plan to fulfill requirements for instruction in the Responsible Conduct of Research (RCR). See SF424 (R&R) Application Guide for instructions.

Mentor, Co-Mentor, Consultant, Collaborators Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Plans and Statements of Mentor and Co-mentor(s)

- The candidate must name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the proposed program. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- Include a statement that the candidate will commit at least 9 person months (75% of full-time professional effort) to the career development program and related career development activities.
- The application must include a statement from the mentor providing: 1) information on their research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of their career to independent research investigator status during the project period of the award; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- Similar information must be provided by any co-mentor. If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any co-mentor is not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of face-to-face meetings.
- The primary mentor must agree to provide annual evaluations of the candidate's progress as required

in the annual progress report.
- If the candidate is proposing to gain experience in a clinical trial as part of his or her research career development, the mentor or co-mentor of the mentoring team must include a statement to document leadership of the clinical trial, and appropriate expertise to guide the applicant in any proposed clinical trials research experience.
- For applicants proposing a clinical trial, ancillary or feasibility study, the mentor or mentoring team must provide evidence of expertise, experience, and ability to guide the candidate in the organization, management and implementation of the proposed clinical trial, ancillary clinical trial, or feasibility study and help him/her to meet timelines.

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators and/or consultants confirming their participation in the project and describing their specific roles. Collaborators and consultants do not need to provide their biographical sketches unless also listed as senior/key personnel. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.
- Advisory committee members (if applicable): Signed statements must be provided by each member of the proposed advisory committee. These statements should confirm their participation, describe their specific roles, and document the expertise they will contribute. Unless also listed as senior/key personnel, these individuals do not need to provide their biographical sketches.

Environmental and Institutional Commitment to the Candidate

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Description of Institutional Environment

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.
- For applicants proposing a clinical trial, ancillary or feasibility study, describe the resources and facilities that will be available to the candidate, including any clinical trial-related resources, such as specialized administrative, data coordinating, enrollment, and laboratory/testing support. If applicable, include a description of the resources and facilities available at international sites.

Institutional Commitment to the Candidate’s Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide assurances that the candidate will be able to devote the required effort to activities under this award.The remaining effort should be devoted to activities related to the development of the candidate’s career as an independent scientist.
- Provide assurances that the candidate will have access to appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations as applicable) to carry out the proposed research plan.

- Provide assurance that appropriate time and support will be available for any proposed mentor(s) and/or other staff consistent with the career development plan.

Other Research Plan Sections

Resource Sharing:

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Individuals are required to comply with the instructions for the Resource Sharing as provided in the SF424 (R&R) Application Guide, with the following additional instructions:

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

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

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

CDC OMB-approved templates may be used (e.g., NCCDPHP template).

Appendix

Limited items are allowed in the Appendix. Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents is allowed in the appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

- For applications not proposing clinical trials, do not complete Section 4 – Protocol Synopsis information or Section 5 - Other Clinical Trial-related Attachments.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

All instructions in the SF424 (R&R) Application Guide must be followed.

Reference Letters

Candidates must carefully follow the SF424 (R&R) Application Guide, **including the time period for when reference letters will be accepted**. Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons Submit Referee Information link and not through Grants.gov.

Optional Components for this NOFO

R&R Subaward Budget Attachment(s)

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

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

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before

their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

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

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

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

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

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

http://grants.nih.gov/support/index.html

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

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

Toll-free: 1-800-518-4726

https://www.grants.gov/web/grants/support.html

support@grants.gov

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

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

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

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

1. Track submission and verify the submission status (tracking should be done initially

regardless of rejection or success).

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices. If the status states "rejected" and there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Electronically submitted applications must be submitted no later than 5:00 PM Eastern Time on the listed application due date.

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

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to the HHS Grants Policy Statement and speak to your Grants Management Specialist.

All HHS/CDC awards are subject to the federal regulations in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Public Health Data:

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Career Development Award Supplemental 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). For further information, please see

revised AR-25.

Human Subjects:

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

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

Note: The sIRB requirement applies to participating sites in the United States.

7. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement
NOTE TO APPLICANTS: THIS IS REQUIRED

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, 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, 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, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to

include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy. **Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "R&R Other Project Information" section of the application.**

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 as an attachment in the "12. Other Attachments" section of the "R&R Other Project Information" section of the application. The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap." Write 'None' in the report if no overlap.

Application Submission
Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. **Paper applications will not be accepted**.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission contact the Application Submission Contacts in Section VII.

Important reminders:

All Senior/Key Personnel (including any Program Directors/Principal Investigators (PD/PIs) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC. See Section III of this NOFO for information on registration requirements.

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under 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 avoiding common errors and submitting, tracking, and viewing applications:

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

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

In order to expedite review, applicants are requested to notify the CDC/NIOSH Scientific Review Officer by email at LEE5@cdc.gov when the application has been submitted. Please include the NOFO number and title, PD/PI name, and title of the application.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy. Any instructions provided here are in addition to the instructions in the policy.

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 and NIOSH mission, all applications submitted to the CDC/NIOSH in support of public health research are evaluated for scientific and technical merit through

the CDC/NIOSH peer review system.

Overall Impact
Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

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 applications proposing a clinical trial, ancillary or feasibility study, the reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the possibility that research support provided through career development awards may be sufficient to support only small feasibility studies.

Candidate

Does the candidate have the potential to develop as an independent and productive researcher?

Are the candidate's prior training and research experience appropriate for this award?

Is the candidate's academic, clinical (if relevant), and research record of high quality?

Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?

Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

For applications proposing a clinical trial, ancillary or feasibility study, does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?

For applications proposing a clinical trial, does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

Career Development Plan/Career Goals and Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career

development, will the clinical trial experience contribute to the applicant's research career development?

Research Plan

- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support of the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
- Will the proposed research lead to an independent line of research for the candidate?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, will the clinical trial experience contribute to the research project?

The following 7 questions apply to applications proposing a clinical trial, ancillary or feasibility study:

- Are the scientific rationale and need for a clinical trial, ancillary cliical trial, or feasibility study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
- Is the clinical trial or ancillary clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of future clinical trial?
- Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
- Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?
- For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and their strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?

- Are there adequate plans for monitoring and evaluating the career development recipient's progress toward independence?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?
- For applications proposing a clinical trial, ancillary or feasibility study, does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary clinical trial, or feasibility study and help him/her to meet timelines?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 9 person months (75% of the candidate's full-time professional effort) will be devoted directly to the research and career development activities described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for the candidate's scientific and professional development of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?

The following 2 questions apply to applications proposing a clinical trial, ancillary or feasibility study:

- Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
- Does the application adequately address the capability and ability to conduct the trial, ancillary clinical trial or feasibility study at the proposed site(s) or centers? If applicable, are there plans to add or drop enrollment centers, as needed, appropriate?

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.

Study Timeline for Clinical Trials

For applications proposing a clinical trial, ancillary or feasibility study: Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

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 Guidelines for the Review of Human Subjects and the HHS/CDC Requirements under AR-1 Human Subjects Requirements.

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 Individuals Across the Lifespan
When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research, Policy for Inclusion of Women and Racial and Ethnic Minorities in Research, and the policy on the Inclusion of Persons Under the Age of 21 in Research.

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

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.

Resubmissions
For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals
Not Applicable.

Revisions
Not Applicable.

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.

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 score.

Limitations of Currently Available Data

Health effects related to the September 11, 2001, terrorist attacks are primarily a result of exposure during the attacks, while responding to the resulting disaster, or while living in the area during the disaster response, remediation, and cleanup efforts. Scientifically identifying the causes of health problems or conditions is typically very difficult because of independent factors unrelated to the terrorist attacks that may contribute to the onset of specific diseases. Likewise, health conditions existing prior to exposures related to the terrorist attacks may also be contributing factors.

Reviewers should consider that a standardized body of pre-existing medical data for all potential study subjects may not exist. In addition, the paucity of reliable, comprehensive environmental measurements could make quantifying exposures very difficult.

Although often it may not be possible to determine the specific cause of an individual's illness or condition, it is critical to promote scientifically rigorous studies and reviews of potential health problems or risk factors among the affected population. Reviewers should consider how well applicants acknowledge and address the limitations in currently available data.

Project Dissemination Plan

Reviewers will assess whether the proposal includes an adequate plan for summarizing and disseminating results. The dissemination plan should include:

- Publication of results in peer-reviewed scientific journals;

- Presentation of results at scientific conferences (specify the target conferences);
- Presentation of findings/progress at the bi-annual WTC Research Recipient meetings; and
- Presentation of results to diverse interested groups or stakeholder organizations.

Project Evaluation Plan

Reviewers will assess whether the proposal includes an adequate plan for evaluating outputs, outcomes, and impacts. The evaluation plan should:

- Identify personnel responsible for evaluating study activities and quality of collected data;
- Describe assessments of the quality and accuracy of collected data;
- Describe training and supervision of personnel gathering and analyzing data;
- Describe the review of recruitment goals and preliminary results; and
- Identify how emerging problems will be resolved.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the candidate, including any prior instruction or participation in RCR as appropriate for the candidate's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the fellow's instruction; 4) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact hours are required); and 5) *Frequency of Instruction* –instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as *ACCEPTABLE* or *UNACCEPTABLE*, and the summary statement will provide the consensus of the review committee. See also: NOT-OD-10-019 and NOT-OD-22-055.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

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 AR-25.

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 NOFO **should include a detailed DMP in the Resource Sharing section of the PHS 398 Career Development Award Supplemental Component** of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators

regarding the requirements for data accessibility, storage, and preservation.

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

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

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

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

CDC OMB-approved templates may be used (e.g., NCCDPHP template).

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate Scientific 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:

- May 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 score.
- Will receive a written critique.

Appeals for initial peer review will not be accepted for applications submitted in response to this NOFO.

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 for programmatic relevance and balance. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Relevance of the proposed research to WTC Health Program priorities and needs.
- Potential for the proposed research to contribute to development of guidelines for improved treatment, diagnosis, intervention, or healthcare for populations covered by the WTC Health Program.
- Potential contribution of the proposed research to a blend or balance of studies that advance an overall understanding of health impacts on the diverse populations covered by the WTC Health Program.
- Results (outputs and outcomes) of prior research (e.g., peer-reviewed publications) awards funded by CDC/NIOSH/WTC Health Program.
- Commitment of the applicant institution and PI to collaborative efforts.
- Adequacy of data management plan.
- Administrative/managerial capability of the applicant institution.
- Availability of funds.

The NIOSH Secondary Review Committee may review, discuss, prioritize, and recommend applications for funding based on classification of projects by WTC subpopulation(s) and relevant diseases/conditions based on program needs.

Review of Risk Posed by Applicants

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR § 75.207.

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this

NOFO.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- Financial stability;
- Quality of management systems and ability to meet the management standards prescribed in this part;
- 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;
- Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
- 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.

3. 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. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the *HHS Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement.

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

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants

Management Officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions as described in Section IV.6. 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. Awards are not transferable from one PD/PI to another.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in CDC-funded studies, the recipient must provide CDC copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement and CDC Administrative Requirements (policies) found on the CDC Office of Financial Resources, Grant, webpage, including of note, but not limited to:

- Federalwide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See Provider Obligations and HHS Nondiscrimination Notice.

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to CDC grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English-proficient individuals, see Fact Sheet on Guidance and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see Disability Info page.
- HHS-funded health and education programs must be administered in an environment free of sexual harassment, see Sex Discrimination Info page.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see Conscience Protections page and Religious Freedom page.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), HHS/CDC awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all CDC grants and cooperative agreements except fellowships.

Additional Requirements (ARs)

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: https://www.archives.gov/.

Specific requirements that apply to this NOFO are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-21: Small, Minority, and Women-Owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

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

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020

Organization specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR-23: Compliance with 45 C.F.R. Part 87

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

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS Policy on Promoting Efficient Spending website.

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

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

Employee Whistleblower Rights and Protections All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, “Enhancement of contractor protection from reprisal for disclosure of certain information” and 48 CFR section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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

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

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

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

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

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

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

Data Management Plan(s)

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

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

The AR-25 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 AR-36 to ensure compliance with this term and condition.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) in eRA Commons annually and financial statements as required in the HHS Grants Policy Statement. The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. For

mentored awards, the Mentor's Report must include an annual evaluation statement of the candidate's progress.

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

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

1) Information on executive compensation when not already reported through the SAM Registration; and

2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement.

Submission of Reports
The Recipient Organization must submit:

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

2. Annual Federal Financial Report (FFR) SF 425 (Reporting) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends**.

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

Content of Reports

1. Yearly Non-Competing Grant Progress Report

The recipient's continuation application/progress report should include:

- **Description of Progress during Annual Budget Period:** Current Budget Period Progress reported on the RPPR form in eRA Commons. 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

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

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 be used to influence practices, procedures, methodologies, etc.?

How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- **Current Budget Period Financial Progress:** Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- **New Budget Period Proposal:** Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- **Project Timeline:** Include planned milestones for the upcoming year (be specific and provide deadlines).
- **New Budget Period Budget:** Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- **Publications/Presentations:** Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- **IRB Approval Certification:** Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.
- **Update of Data Management Plan:** The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

2. Annual Federal Financial Reporting

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

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

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

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: eRA Commons Registration & Accounts.

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.

3. Final Reports

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

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

Specific guidance for the final report is available under Grant Closeout at the NIOSH OEP website.

4. Termination

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

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

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to

comply with the terms and conditions of the award;

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, tracking application status, FFR submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 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

General Grants Information (Questions regarding application instructions, application processes, and grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-637-3015

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

Scientific/Research Contact
James Yiin, PhD
Scientific Program Official
Office of Extramural Programs (OEP)
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Telephone: 513-841-4271
Email: JCY5@cdc.gov

Peer Review Contact
Laurel Garrison, MPH
Scientific Review Officer
Office of Extramural Programs (OEP)
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Telephone: (513) 533-8324
Email: LEE5@cdc.gov

Financial/Grants Management Contact
Regina Mobley
Grants Management Specialist
Office of Grant Services (OGS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
Telephone: 678-475-4986
Email: TLZ7@cdc.gov

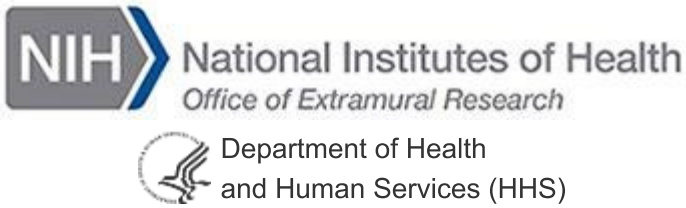
Section VIII. Other Information

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

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

Awards are made under the authorization of Section 301 of the Public Health Service Act as amended (42 U.S.C. 241); Federal Regulations 42 CFR Part 52 and 45 CFR Part 75, and the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328); codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. §§ 300mm – 300mm–62.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices



NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.