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)

Notice of Funding Opportunity (NOFO) Title

Exploratory/Developmental Research for World Trade Center Health Program Evidence-based Strategies to Improve Treatment Effectiveness, Diagnostic Practices, and Program Evaluation (R21)

Activity Code

R21 Exploratory/Developmental Research Grant

Announcement Type

New

Related Notices

None

Funding Opportunity Number (FON)

RFA-OH-25-001

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

NIOSH supports exploratory and developmental research (R21) which addresses diagnostic or treatment uncertainty with respect to individuals receiving monitoring and/or treatment under subtitle C of the James Zadroga 9/11 Health and Compensation Act of 2010 as amended.

The Zadroga Act lists three broad research areas:

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.

The World Trade Center (WTC) Health Program intends to increase opportunities for research on innovative approaches, interventions, techniques, or methods to improve treatment and diagnostic effectiveness through intervention, and support program evaluation.

The WTC Health Program seeks to achieve a suitable mix of scientifically robust research projects which assess the feasibility of enhancing interventions and program evaluations to improve diagnosis, treatment, care, and well-being of 9/11-exposed populations.

Research areas of interest include clinical, screening, diagnostic, epidemiological, treatment, prevention, translation, and program evaluation. WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the populations of interest.

The research should consider health equity initiatives in design, where possible. Opportunities for future health effects research involving vulnerable groups of persons (e.g., minorities, women, children, and other potentially disadvantaged groups) who were exposed to the 9/11 attacks and aftermath are of special interest. Research is needed to identify at-risk groups, characterize the health burden, and to inform care.

This WTC Health Program R21 Notice of Funding Opportunity (NOFO) is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development which assess the feasibility of new areas of investigation with the potential to enhance treatment effectiveness and diagnostic practices. These studies may lead to breakthroughs in a particular area, or to the development of new

interventions, techniques, agents, methodologies, models, or approaches with major clinical impacts. These studies are expected to break new ground or extend prior discoveries toward new directions or uses. Applicants are expected to propose research for which there is likely to be minimal or no preliminary data.

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

May 7, 2024

Open Date (Earliest Submission Date)

June 3, 2024

Letter of Intent Due Date(s)

September 27, 2024 (LOI recommended but not required)

Application Due Date(s)

October 29, 2024

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

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

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

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

March 2025

Advisory Council Review

April 2025

Earliest Start Date

July 1, 2025

Expiration Date

November 28, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) 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.

Note: The Research Strategy component of the Research Plan is limited to **6** pages.

Page Limitations: Pages that exceed the page limits described in this NOFO will be removed and not forwarded for peer review.

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

for review.

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

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.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Statutory Authority

The World Trade Center (WTC) Health Program was established by Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111-347, as amended by Pub. L. 114-113, Pub. L. 116-59, Pub. L. 117-328, and Pub. L. 118-31 adding Title XXXIII to the Public Health Service (PHS) Act (codified at 42 U.S.C. 300mm - 300mm-64). 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, 117-328, and 118-31. 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, 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

NIOSH supports exploratory and developmental research projects (R21) that address issues related to diagnostic or treatment uncertainty with respect to individuals receiving monitoring and/or treatment under subtitle C 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, 117-328, and 118-31).

The WTC Health Program intends to increase opportunities for research on new, innovative approaches, interventions, techniques, or methodologies to improve treatment and diagnostic effectiveness through intervention, as well as support program evaluation.

The WTC Health Program seeks to achieve a suitable mix of scientifically robust research projects which assess the feasibility of enhancing interventions and program evaluations

to improve diagnosis, treatment, care, and well-being of 9/11-exposed populations.

Research areas of interest include clinical, screening, diagnostic, epidemiological, treatment, prevention, translation, and program evaluation. WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the populations of interest.

The research should consider health equity initiatives in design, where possible. Opportunities for future health effects research involving vulnerable groups of persons (e.g., minorities, women, children, and other potentially disadvantaged groups) who were exposed to the 9/11 attacks and aftermath are of special interest. Research is needed to identify at-risk groups, characterize the health burden, and to inform care.

This WTC Health Program R21 Notice of Funding Opportunity (NOFO) is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development which assess the feasibility of new areas of investigation with the potential to enhance treatment effectiveness and diagnostic practices. These studies may lead to breakthroughs in a particular area, or to the development of new interventions, techniques, agents, methodologies, models, or approaches with major clinical impacts. These studies are expected to break new ground or extend prior discoveries toward new directions or uses. Applicants are expected to propose research for which there is likely to be minimal or no preliminary data.

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).

Major areas of research interest
Research areas of interest include clinical, screening, diagnostic, epidemiological, treatment, prevention, translation, and program evaluation. WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the population targeted for the research project.

NIOSH is soliciting exploratory and developmental research grant applications (R21) to increase support and focus on assessing the feasibility, development, and effectiveness of methods, practices, interventions, and programs related to evidence-based strategies to improve treatment effectiveness, diagnostic practices, and program evaluation. In the following areas:

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.

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.

Screening Research: Projects that evaluate current, or facilitate the development of, new/improved, methods to detect certain disorders or health conditions.

Diagnostic Research: Projects that evaluate current, or facilitate the development of, new/improved, methods to identify diseases, disorders, or conditions.

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.

Proposed projects should consider health equity initiatives in design, where possible. Opportunities for future health effects research involving vulnerable groups of persons (e.g., minorities, women, children, and other potentially disadvantaged groups) who were exposed to the 9/11 attacks and aftermath are of special interest. Research is needed to identify at-risk groups, characterize the health burden, and inform care.

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.

Relevant diseases or conditions include, but are not limited to:

- Respiratory diseases
- Cancer (including detection/diagnosis of pre-malignant changes)
- Cardiovascular Disease
- Psychological resilience and well-being
- Persistent psychiatric conditions such as posttraumatic stress, anxiety and depressive disorders
- Cognitive changes
- Aging the impacts of aging on those impacted by 9/11 illness and injury (e.g., premature aging, optimizing adaptation for productivity)

- Neurological Diseases
- Aerodigestive health
- Birth and Reproductive Outcomes
- Multisystem or auto-immune diseases
- Emerging conditions identified by WTC Health Program surveillance activities. Includes diseases/conditions requiring further program consideration. A list of these diseases/conditions is found at https://www.cdc.gov/wtc/received.html, in the section titled, *Petitions Received and WTC Health Program Responses*.

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 to 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 and mitigation of health effects from future disasters.

The WTC Health Program seeks to achieve a suitable mix of scientifically robust research projects which assess the feasibility of enhancing interventions and program evaluations to improve diagnosis, treatment, care, and well-being of 9/11-exposed populations.

Research areas of interest include clinical, screening, diagnostic, epidemiological, treatment, prevention, translation, and program evaluation. WTC responders, screening-eligible WTC survivors, and certified-eligible WTC survivors comprise the population targeted for the research project.

The research should consider health equity initiatives in design, where possible. Opportunities for future health effects research involving vulnerable groups of persons (e.g., minorities, women, children, and other potentially disadvantaged groups) who were exposed to the 9/11 attacks and aftermath are of special interest. Research is needed to identify at-risk groups, characterize the health burden, and to inform care.

WTC Health Program applicants are strongly encouraged to review the WTC Health Program Research webpage which 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).

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 which 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 conducted under the Zadroga Act includes epidemiologic and other research studies on WTC-related health conditions or emerging conditions among (1) WTC responders, 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.

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.

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.

Population of Focus

The population of focus 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.

The WTC Health Program recognizes that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams. There are many benefits which flow from a diverse scientific workforce, including fostering scientific innovation, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved populations participate in and benefit from research, and enhancing public trust.

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 financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary and the How to Apply - 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)

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 $4.0M; and assumes a 2-year period of performance.

Anticipated number of awards is 4 to 8.

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

Award Budget

Up to $500,000 in total costs (direct and indirect costs; including consortium F&A costs) for the 2-year period of performance.

No more than $365,000 in total costs may be requested in either year.

Award Project Period

2 years

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement 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)

Local 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 Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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 NIH 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 2-year period of performance limit, the total cost limit of $500,000 (including consortium F&A costs) for the 2-year period of performance or the total cost limit of $365,000 in either year 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 Research Strategy component of the Research Plan is limited to **6** pages. This 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.

Special Requirements

You must specify the **WTC subpopulation(s) under study** (see Section I. Population of Focus 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 or conditions** listed in Section I of this announcement 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 **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 "11. Other Plan(s)" section of the "PHS 398 Research Plan" 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). Other examples of DMPs may be found at USGS. See Section IV, Content and Form of Application Submission for information.

Note to Applicants

Pre-application Public Information Sessions will be conducted in mid-September to address questions from prospective applicants regarding current research funding opportunities published by the WTC Health Program. During the sessions, CDC, NIOSH, and WTC Health Program staff will provide information on the scope of this and other relevant announcements, the application process, the peer review process, and answer questions about the NOFOs (note the staff will not take comments). Interested applicants wanting to learn more about the NOFOs and ask questions, please check the OEP website for dates, times and call-in methods, which will be posted no later than August 1.

WTC Health Program Reference Documents

Interested applicants are strongly encouraged to review the WTC Health Program Research webpage, which 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).

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).

Required Registrations
Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) How to Apply - Application Guide to be eligible to apply for or receive an award. 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

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

- System for Award Management (SAM) (the replacement system for the Central Contractor Registration) 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.

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) in Organizations/Institutions
Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. **CDC does not make awards to individuals directly.** Individuals from

organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide.

When multiple PDs/PIs are proposed, NIOSH requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communications between the PDs/PIs and the NIOSH, for assembling the application materials outlined below, and for coordinating progress reports. The Contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs.

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.

As defined in the HHS Grants Policy Statement, applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. This means that the HHS/CDC 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.

Section IV. Application and Submission Information

1. Requesting an Application Package

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

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

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

It is critical that applicants follow the Research (R) Instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this NOFO to do otherwise. Conformance to the requirements in the How to Apply - 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 activity
- Short summary of the 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 How to Apply Application Guide and the Table of Page Limits must be followed. with the following exceptions or additional requirements for this NOFO:

- The Research Strategy component of the Research Plan narrative is limited to **6** pages. These page limits are the totals for all text, tables, graphs, figures, diagrams, and charts in this component.
- Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 100 pages for all appendices.

All page limitations described in this individual NOFO must be followed. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review.

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.

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 How to Apply 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 How to Apply - Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the How to Apply - Application Guide must be followed.

R&R Other Project Information
All instructions in the How to Apply - Application Guide must be followed. 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, Special Requirements for information).
- **Project Dissemination Plan** (see Section V, Additional Review Considerations for information)
- **Project Evaluation Plan** (see Section V, Additional Review Considerations for information)
- **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 How to Apply - Application Guide must be followed.

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

R&R Budget
All instructions in the How to Apply - Application Guide must be followed. For this NOFO, CDC/NIOSH requires a detailed budget information for the initial budget year and a budget for the second 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 WTC Health Program research meetings which are held bi-annually in New York City (NYC).

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

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

Introduction

1. Introduction to Application (not applicable to this NOFO).

Research Plan Section

2. Specific Aims state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. Research Strategy the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

4. Progress Report Publication List (not applicable to this NOFO)

Other Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Other Plan(s) - attach **Data Management Plan (DMP)** here, if applicable.

12. Authentication of Key Biological and/or Chemical Resources

Appendix

13. Appendix

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

Additional Components for this NOFO

a. Project Dissemination Plan - See Section V, Additional Review Considerations for information.

b. Project Evaluation Plan - See Section V, Additional Review Considerations for information.

c. Study Information, including **WTC Subpopulation under study** and **Primary Diseases/Conditions** - See Section III, Special Requirements for information.

Please note: the Project Dissemination Plan and Project Evaluation Plan, Study Information as well as Duplication of Efforts should be included as attachments in the "12. Other Attachments" section of the "R&R Other Project Information" section of the application. When uploading documentation into this application package, clearly label the documents for easy identification.

Applicants that plan to collect public health data must submit a **Data Management Plan (DMP)** in the "11. Other Plan(s)" section of the "PHS 398 Research Plan" Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for 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);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- 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).

The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

CDC OMB-approved templates may be used (e.g., NCCDPHP template). Other examples of DMPs may be found at USGS.

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

How to Apply - Application Guide

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 How to Apply - 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 **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the How to Apply - Application Guide must be followed.

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 How to Apply - Application Guide must be followed.

Optional Components for this NOFO:

R&R Subaward Budget Attachment(s)
All instructions in the How to Apply - Application Guide must be followed.

PHS Assignment Request
All instructions in the How to Apply - Application Guide must be followed.

3. 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.

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 How to Apply Application Guide.

4. Intergovernmental Review (E.O. 12372)

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal

Programs. No action is needed.

5. 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 "11. Other Plan(s)" section of the "PHS 398 Research Plan" Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

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.

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 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.

6. Other Submission Requirements and Information

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.

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 and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject-related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to 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 by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

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.

For this particular NOFO, note the following:

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

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

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

Significance
Does the project address important needs or critical barriers to help determine physical and mental health conditions which have persisted, and new symptoms and conditions which have emerged, in people exposed to the 9/11 disaster? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practices be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions used in the World Trade Center Health Program, occupational health, or public health? What is the potential impact of the project on occupational health and safety or public health?

In addition, for applications proposing clinical trials:

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well-supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the program directors/principal investigators, collaborators, and other researchers well-suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organizational structure appropriate for the project? If Early-Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? Do the investigators have a successful track record in public health research? Is there evidence of past collaborations with the proposed research team? Have previous research results provided high-quality outputs and contributed to improvements in public health practice and population health?

In addition, for applications proposing clinical trials:

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Primary Importance to the WTC Health Program: Does the application have a significant potential for immediate or near-term improvement in the diagnosis and treatment of WTC-related health conditions, and/or expand knowledge about physical and mental health conditions that may be related to the September 11, 2001, terrorist attacks?

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

In addition, for applications proposing clinical trials:

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

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

aspects be managed? Does the proposed project timeline include clearly established objectives for which progress will be measured objectively by defined methods? Are the analytic plans clear, consistent with the research questions, and appropriate for the study design and data available? Does the application propose use of evidence-based interventions or strategies in the research plan? Are outputs identified and measures/metric to assess outcomes included? Does the application describe how the results from the research will be disseminated and ultimately used?

If the project involves collaboration with the current Clinical Centers of Excellence, Data Centers, or the WTC Health Registry, are appropriate letters of support included in the application?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address

1) the protection of human subjects from research risks, and

2) 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), justified in terms of the scientific goals and research strategy proposed?

In addition, for applications proposing clinical trials:

Does the application adequately address the following, if applicable:

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, ensure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? For planned or potential collaborations, is the commitment and cooperation of other interested parties adequate as evidenced by letters of support specifying the nature and extent of their involvement?

In addition, for applications proposing clinical trials:

If proposed, 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 at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate? If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in using secure, accurate, and timely methods; and (4) operate within the proposed organizational structure?

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

Protections for Human Subjects
If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the

justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

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 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 NIH guideline and CDC policies on the Inclusion of Women and Racial and Ethnic Minorities in Research and the Inclusion of Persons Under 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 Animals 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
Not Applicable.

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.

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

Study Timeline

For applications proposing clinical trials:

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)?

Additional Review Considerations

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

Generalizability and Limitations of Currently Available Data

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.

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.

Applications from Foreign Organizations

Not Applicable.

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.

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.

The budget can include both direct costs and indirect costs as allowed. Indirect costs could include the cost of collecting, managing, sharing and preserving data.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated

federal indirect cost rate agreement or cost allocation plan approval letter.

2. Review and Selection Process

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

As part of the scientific peer review, all applications:

- 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 of initial peer review will not be accepted for applications submitted in response to this NOFO. The decision to fund or not to fund an organization that applied to a NOFO is not appealable at CDC. Similarly, the score and ranking awarded to an application is not appealable at CDC.

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 may be considered by the WTC Health Program Secondary Review Panel (SRP) 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.

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 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 review of risk may impact award eligibility.

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. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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 their 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.

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 grantee's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative and Additional Policy Requirements

CDC Administrative Requirements

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

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

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-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-37: Prohibition on certain telecommunications and video 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. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

Language Access for Persons with Limited English Proficiency: Recipients of federal

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

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

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

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

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

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

This 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 Additional Requirement 36 to ensure compliance with this term and condition. See AR-36 for the full text.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually and financial statements as required in the HHS Grants Policy Statement.

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

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

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

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

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

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

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 RPPR 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 **120 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 120 days after the end of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

Organizations may verify their current registration status by running the List of Commons Registered Organizations query found at: 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 grantee's final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers,

practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- **Publications; Presentations; Media Coverage:** Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- **Final Data Management Plan:** Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long-term preservation of the data.

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
Christina Park

Grants Management Officer
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: (404) 498-5014
Email: LSK1@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 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, 117-328, and 118-31); codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. 300mm - 300mm-64.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

National Institutes of Health
Office of Extramural Research
Department of Health and Human Services (HHS)
USA.gov Government Made Easy
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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.