# Department of Health and Human Services

# Part 1. Overview Information

**Participating Organization(s)**

Centers for Disease Control and Prevention (CDC)

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

**Components of Participating Organizations**

National Institute for Occupational Safety and Health (NIOSH)

**Funding Opportunity Title**

## Exploratory/Developmental Grants Related to the World Trade Center Survivors (R21-No Applications with Responders Accepted)

**Activity Code**

R21 Exploratory/Developmental Research Grant

**Announcement Type**

Reissue of RFA-OH-22-004

**Related Notices**

None

**Notice of Funding Opportunity (NOFO) Number**

## RFA-OH-24-003

**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 projects (R21) that address issues related to diagnostic or treatment uncertainty with respect to individuals receiving monitoring and/or treatment under subtitle B of the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328).

To help address the Zadroga Act research mandate, as supported by the World Trade Center (WTC) Health Program and in consultation with the WTC Health Program Scientific/Technical Advisory Committee, NIOSH is soliciting applications for scientifically rigorous research (42 U.S.C. §300mm–51) among screening-eligible and certified-eligible WTC survivors and similarly exposed populations in New York City in Manhattan between Houston Street and 14th Street and in Brooklyn to help answer critical questions about:

- 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.

A major area of research interest of this announcement also includes improving the healthcare and well-being of at-risk survivor populations including minority groups, women exposed while pregnant or of reproductive age, the elderly, adolescents, and other minor children. 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.

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.

In addition to screening-eligible and certified-eligible WTC survivors, 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.

The NIOSH/WTC Health Program R21 grant 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 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 approaches 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**

August 16, 2023

**Open Date (Earliest Submission Date)**

November 1, 2023

**Letter of Intent Due Date(s)**

November 1, 2023 (LOI recommended but not required)

**Application Due Date(s)**

December 5, 2023

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

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

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

Service Desk via https://www.era.nih.gov/need-help.

E-mail: commons@od.nih.gov

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

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

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

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

**AIDS Application Due Date(s)**

Not Applicable

**Scientific Merit Review**

March 2024

**Advisory Council Review**

April 2024

**Earliest Start Date**

July 1, 2024

**Expiration Date**

January 4, 2024

**Due Dates for E.O. 12372**

Not Applicable

**Required Application Instructions**

It is critical that applicants follow the 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 not accepted for review.**

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

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

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   Apply Online Using ASSIST
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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# Part 2. Full Text of Announcement

## Section I. Notice of Funding Opportunity Description

### Statutory Authority

The World Trade Center Health Program is authorized under Section 301 of the Public Health Service Act as amended (42 U.S.C. 241) and the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113,

116–59 and 117-328); codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. §§ 300mm – 300mm–62. The authority for this specific research is found in Section 3341 of the Zadroga Act, as amended (42 U.S.C. §§ 300mm–51).

## Background

The World Trade Center (WTC) Health Program is administered by the National Institute for Occupational Safety and Health (NIOSH). Program information is available at the WTC Health Program website. The James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111–347 (hereafter referred to as "the Zadroga Act") was signed by President Obama on January 2, 2011, and was re-authorized on December 18, 2015 (the Consolidated Appropriations Act, 2016, Public Law 114–113), and further amended by Public Laws 116–59 and 117-328. The Zadroga Act established monitoring and treatment activities for responders and survivors of the September 11, 2001, terrorist attacks and requires the establishment (under Subtitle C) of a research program on health conditions resulting from the attacks.

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

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

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

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

## Purpose

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 B of the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113, 116–59 and 117-328).

To help address the Zadroga Act research mandate, as supported by the WTC Health Program and in consultation with the WTC Health Program Scientific/Technical Advisory Committee, NIOSH is soliciting applications for scientifically rigorous research (42 U.S.C. §300mm–51) among screening-eligible and certified-eligible WTC survivors and similarly exposed populations in New York City in Manhattan between Houston Street and 14th Street and in Brooklyn to both address critical questions about physical and mental health conditions and provide practical treatment and diagnostic benefits for enrollees.

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.

In addition to screening-eligible and certified-eligible WTC survivors, proposed research can include 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.

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 NIOSH/WTC Health Program R21 grant 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 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. Applications for long-term projects requiring preliminary data are solicited under other grant mechanisms (e.g., R01 or U01 projects) and will not be accepted for the R21 funding mechanism.

**Major areas of WTC Survivor research interest** include, but are not limited to, the following:

- 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.

A major area of research interest of this announcement also includes improving the healthcare and well-being of at-risk survivor populations including minority groups, women exposed while pregnant or of reproductive age, the elderly, adolescents, and other minor children.

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

Applications should clearly state:

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

**Types of clinical research areas that will be considered for potential projects include, but are not limited to:**

**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.

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

**Omics Research:** Projects that facilitate improvement in methods/procedures for the prediction of disorders by identifying and understanding how genes and illnesses may be related (e.g., identification of phenotypes and biomarkers). Research in this area may explore ways in which a person’s genes make him or her more or less likely to develop a disorder or respond to a medication.

**Epidemiological/Clinical Research:** Projects that seek to identify the patterns, causes, and control of disorders among the WTC population, including women and those exposed to 9/11 as children. These projects will also identify, implement, and improve research

methods.

**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.

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

**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
- 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 productive aging)
- Neurological Diseases
- Aerodigestive health
- Birth and Reproductive Outcomes
- Multisystem or auto-immune diseases
- Other Emerging conditions – research supported by evidence from existing surveillance, research, or concerns raised by the 9/11-exposed population, which point to either a new appearance of a WTC-related health condition or a new understanding of an existing WTC-related health condition.

Among many health conditions that may be explored, there are several conditions that have come to light because of concerns expressed by the affected population. These health conditions include, but are not limited to, endocrine-related disorders, including metabolic syndrome; reproductive health outcomes, such as polycystic ovary syndrome (PCOS), endometriosis, and infertility; autoimmune and neurodegenerative diseases; and cancer among individuals exposed to the WTC disaster at younger ages (18 years of age or younger).

In response to health equity initiatives, 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 September 11, 2001, terrorist

attacks and aftermath are of special interest. Research is needed to identify at-risk groups, characterize the health burden, and inform care. Potential projects include (but are not limited to) research targeted to:

- Develop and apply methods for identifying a cohort of eligible young adult study subjects (exposed and control groups) and determine their willingness to participate in future health effects research. These methods include, but are not limited to, community-based approaches to recruitment that engage existing outreach and education partners and mixed methods research to assess health concerns and interests in research participation.
- Develop methods to systematically determine whether there are unique vulnerabilities and health disparities in groups within the population of individuals exposed to the 9/11 attacks and its aftermath.

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 exploratory/developmental 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;
- improve the healthcare and well-being of the at-risk survivor populations including minority groups, women exposed while pregnant or of reproductive age, the elderly, adolescents, and other minor children; and
- apply lessons learned from 9/11 to improve response to and mitigation of health effects from future disasters.

NIOSH seeks to achieve a suitable mix of projects that help advance treatment effectiveness and the understanding of health and well-being impacts related to the September 11, 2001, terrorist attacks among WTC survivors.

Increased knowledge of the characteristics of WTC-related illnesses and disorders, such as pathology, prognosis, latency, and the effects of other risk factors and comorbidities, is critical for achieving improved treatment and intervention protocols. Scientific evaluation of the translation of WTC Health Program research outputs into practical benefits enhances research integration and expedites research-to-care program objectives.

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

## Healthy People 2030 and other National Strategic Priorities

The WTC research program funded by this NOFO will contribute to the CDC strategic

goal, in alignment with an HHS strategic goal and objectives found in Healthy People 2030, to increase the number of communities that protect and promote health and safety and prevent illness and injury to improve the safety, quality, affordability, and accessibility of health care.

## Public Health Impact

A growing body of evidence suggests that significant health conditions have emerged 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, screening-eligible WTC survivors, and certified-eligible WTC survivors under treatment and individuals who were exposed within a geographic area related to the September 11, 2001, terrorist attacks in a manner similar to the exposure within such geographic area experienced by individuals meeting the eligibility criteria under section 3311(a)(2) or 3321(a)(1)(B); and (2) sampled populations outside the New York City disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

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

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

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

CDC/NIOSH solicited public comments regarding research priorities for WTC Health Program research projects on WTC survivors (adults and children) and similar survivor populations south of 14th street in Manhattan and in Brooklyn. The WTC Health Program's research program helps answer critical questions about potential 9/11-related physical

and mental health, as well as diagnosing and treating health outcomes on the List of WTC-Related Health Conditions.

The public comments (closed August 23, 2021) are shared in Docket CDC-2021-0071 at https://www.regulations.gov/document/CDC-2021-0071-0001.

## Relevant Work

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

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

## Target Population

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

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.

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

## Collaboration/Partnerships

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

### Ancillary Studies/Secondary Analysis of Existing Data

Applicants considering projects that depend on interaction or collaboration with the Data

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

**Data Center and WTC Health Registry Contacts**

*Fire Department of New York*

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

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

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

*Icahn School of Medicine at Mount Sinai*

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

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

*NYC Health and Hospitals Corporation*

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

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

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

*WTC Health Registry*

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

## Evaluation/Performance Measurement

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

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

evidence-based activities, and demonstrating beneficial results and impact of federal funding.

## Translation Plan

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

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

# Section II. Award Information

**Funding Instrument**

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

**Application Types Allowed**

New
Resubmission

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

**Clinical Trial?**

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

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 meritorious 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 any single 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 Institutions**

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

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

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

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

**Responsiveness**

See Section I. Target Population for descriptions of allowed WTC subpopulation. No applications with responders are accepted for this NOFO.

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 any single 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.

**Note to Applicants**
You must specify the **WTC Subpopulation under study** (WTC survivors; see Section I. Target Population for descriptions). No applications with responders are accepted for this NOFO.

You must also include the **primary diseases or conditions** (e.g., **respiratory disease**, **adult mental health**, **cancer**, **children's research** or **emerging conditions**) that you propose to study, with a brief description of the diseases or conditions.

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

Applicants who plan to collect public health data must submit a **Data Management Plan (DMP)** in the Resource Sharing Plan 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). See Section IV, Content and Form of Application Submission and Section V, Additional Review Considerations for information.

The NIOSH Secondary Review Committee (SRC) may categorize and prioritize projects by WTC subpopulation and relevant diseases/conditions listed in Section I of this announcement based on program needs.

**WTC Health Program Reference Documents**

The WTC Health Program Research Publication Library

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

The WTC Research Grant Project Information Dashboard

The funding dashboard includes all research projects awarded since 2011 (the year that

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

Public Input on the Scope of WTC Health Program Research Activities on WTC Survivors (Docket CDC-2021-0071)

CDC/NIOSH solicited public comments regarding research priorities for WTC Health Program research projects on WTC survivors (adults and children) and similar survivor populations south of 14th street in Manhattan and in Brooklyn. The WTC Health Program's research program helps answer critical questions about potential 9/11-related physical and mental health, as well as diagnosing and treating health outcomes on the List of WTC-Related Health Conditions. The public comments for Docket CDC-2021-0071 closed on August 23, 2021.

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

**Required Registrations**
**Applicant Organizations**

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

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

- System for Award Management (SAM)– Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in

place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov – Applicants must have an active SAM registration in order to complete the Grants.gov registration. All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

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

must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission; therefore the applicant organization must ensure that their Grants.gov AOR credentials are active. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

**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)**
This NOFO invites applications from both experienced researchers and researchers who are at the early stage of their independent careers or have not had substantial prior NIH/CDC funding.

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

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 SF424 (R&R) 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.

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

## 2. Cost Sharing

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

## 3. Additional Information on Eligibility

**Number of Applications**
Applicant organizations may submit more than one application, provided that each application is scientifically distinct. As defined in the HHS Grants Policy Statement, applications received in response to the same NOFO generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. The CDC/NIOSH will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

The CDC/NIOSH will not accept duplicate or highly overlapping applications under review at the same time per 2.3.7.4 Submission of Resubmission Application. This means that the CDC/NIOSH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of

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

# Section IV. Application and Submission Information

## 1. Requesting an Application Package

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

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

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

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

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

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

## 2. Content and Form of Application Submission

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

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

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

**Letter of Intent**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review. By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:

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

**Page Limitations**

All page limitations described in the SF424 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.

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

**Instructions for Application Submission**

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen. The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this NOFO.

***Required Components for this NOFO***

**SF424(R&R)**

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

**PHS 398 Cover Page Supplement**

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

**R&R Other Project Information**

All instructions in the SF424 (R&R) Application Guide must be followed. 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 under study** and **Primary Diseases/Conditions** (see Section III, Note to Applicants for information).
- **Project Dissemination Plan** (see Section V, Additional Review Considerations for information)
- **Project Evaluation Plan** (see Section V, Additional Review Considerations for information)
- **CDC Risk Questionnaire** with supporting documentation (see Section IV, Other Submission Requirements and Information for instructions)
- **Duplication of Efforts** (see Section IV, Other Submission Requirements and Information for instructions). Write 'None' if no overlap.

**Project/Performance Site Location(s)**

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

**R&R Senior/Key Person Profile (Expanded)**

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

**R&R Budget**

All instructions in the SF424 (R&R) 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 required 2-day meeting for WTC Health Program research recipients. The meetings are held bi-annually in New York City (NYC) and may alternate between webinars and in-person meetings.

**PHS 398 Research Plan**

All instructions in the SF424 (R&R) 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** (for Resubmission applications ONLY; Revision applications are not allowed for this NOFO) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the 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)** - CDC's Data Management Plan (DMP) policy applies to this NOFO. See below and Section V, Additional Review Considerations for information.

**11. Other Plan(s)** - NIH's Data Management and Sharing (DMS) Plan policy is not applicable to this NOFO. Follow the DMP instructions in this NOFO instead.

**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, Note to Applicants for information.

> **Please note:** the Project Dissemination Plan and Project Evaluation Plan, Study Information as well as CDC Risk Questionnaire and 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.

**Resource Sharing Plan(s)**

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

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

application for CDC funds.

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

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

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

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

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

**Study Record: PHS Human Subjects and Clinical Trials Information**

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

**Delayed Onset Study**

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

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

***Optional Components for this NOFO***

**R&R Subaward Budget Attachment(s)**
All instructions in the SF424 (R&R) Application Guide must be followed.

**PHS Assignment Request**
All instructions in the SF424 (R&R) Application Guide must be followed.

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

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique

entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

## 4. Submission Dates and Times

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

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

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

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

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

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

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

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

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

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

Toll-free: 1-800-518-4726

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

support@grants.gov

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

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

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

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

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

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

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

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

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

## 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

## 6. Funding Restrictions

**Expanded Authority:**

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

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

**Public Health Data:**

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

**Data Management Plan:**

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

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

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination). For further information, please see revised AR-25.

**Human Subjects:**

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

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

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

## 7. Other Submission Requirements and Information

**Risk Assessment Questionnaire Requirement**

**NOTE TO APPLICANTS: THIS IS REQUIRED**

CDC is required to conduct pre-award risk assessments to determine the risk an applicant

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

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

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

**Duplication of Efforts**

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

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

**Application Submission**

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

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

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

**Important reminders:**

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

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

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

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

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

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

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

**Post Submission Materials**

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

## Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission and NIOSH mission, all applications submitted to the CDC/NIOSH in support of public health research are evaluated for scientific and technical merit through the CDC/NIOSH peer review system.

For this particular announcement, 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/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

**Scored Review Criteria**

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

**Significance**

Does the project address 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 WTC survivors 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 Guidelines for the Review of Human Subjects and the HHS/CDC Requirements under AR-1 Human Subjects Requirements.

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

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

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

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

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

**Renewals**
Not Applicable.

**Revisions**
Not Applicable.

### Dual Use Research of Concern

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

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/Documents/durc-companion-guide.pdf and 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.

#### Limitations of Currently Available Data

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

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

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

#### Project Dissemination Plan

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

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

#### Project Evaluation Plan

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

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

### 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.

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see AR-25.

*New Additional requirement:* CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a **Data Management Plan (DMP)** for each collection of public health data.

Investigators responding to this NOFO **should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component** of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

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

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

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

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

### 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.

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

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

The NIOSH Secondary Review Committee may review, discuss, prioritize, and recommend applications for funding based on classification of projects by WTC subpopulation and relevant diseases/conditions listed in Section I of this announcement based on program needs.

**Review of Risk Posed by Applicants**

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

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

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

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

- Financial stability;
- Quality of management systems and ability to meet the management standards prescribed in this part;
- History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
- The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

## 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

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

# Section VI. Award Administration Information

## 1. Award Notices

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

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

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

Recipients must comply with any funding restrictions as described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

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

## 2. Administrative and National Policy Requirements

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

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

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

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

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

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

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

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

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

Specific requirements that apply to this NOFO are the following:

**Generally applicable ARs:**

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

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

AR-36: Certificates of Confidentiality

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

**Organization specific ARs:**

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

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

**Federal Funding Accountability and Transparency Act of 2006** Federal Funding Accountability and Transparency Act of 2006 (FFATA), Public Law 109–282, as amended

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

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

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

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

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

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

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

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

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

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

### Data Management Plan(s)

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

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

The AR-25 outlines the components of a DMP and provides additional information for

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

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

**Cooperative Agreement Terms and Conditions of Award**

Not Applicable

## 3. Reporting

When multiple years are involved, 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 form (instructions) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

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

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

**Content of Reports**
**1. Yearly Non-Competing Grant Progress Report**

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

- **Description of Progress during Annual Budget Period:** Current Budget Period Progress reported on the RPPR form in eRA Commons. Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- **Research Aims:** list each research aim/project

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

*Leadership/Partnership*: list project collaborations and describe the role of external partners.

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

outside of the study. Questions to consider in preparing this section include:

*How will the scientific findings be translated into public health practice or inform public health policy?*

*How will the project improve or effect the translation of research findings into public health practice or inform policy?*

*How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?*

*How will the findings advance or guide future research efforts or related activities?*

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

*How will this project lead to improvements in public health?*

*How will the findings, results, or recommendations be used to influence practices, procedures, methodologies, etc.?*

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

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

## 2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of

unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

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

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

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

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: eRA Commons Registration & Accounts. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide.

### 3. Final Reports

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

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If

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

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

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

## 4. Termination

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

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

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

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

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

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

# Section VII. Agency Contacts

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

**Application Submission Contacts**

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and

warnings, documenting system problems that threaten submission by the due date, tracking application status, FFR submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

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

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

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

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

**Financial/Grants Management Contact**
Cynthia Thompson
Grants Management Specialist
Office of Grant Services (OGS)
Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-2714
Email: CBT1@cdc.gov

## Section VIII. Other Information

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

**Authority and Regulations**

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

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

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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.