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 funding opportunity announcement (FOA) might differ from those used by the HHS National Institutes of Health (NIH). If written guidance for completing this application is not available on the CDC website, then CDC will direct applicants elsewhere for that information.

Components of Participating Organizations

National Institute for Occupational Safety and Health (NIOSH)

Funding Opportunity Title

World Trade Center Health Research related to WTC Survivors (U01-No Applications with Responders Accepted)

Activity Code

U01 Research Project – Cooperative Agreements

Announcement Type

New

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-OH-22-004

Companion 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

To help address the Zadroga Act research mandate (Public Law 111–347, as amended by Public Laws 114–113 and 116–59), as supported by the World Trade Center (WTC) Health Program 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 enrolled 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 wellbeing of at-risk survivor populations including minority groups, women exposed while pregnant or of reproductive age, the elderly, adolescents, and other minor children.

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 who have been identified as eligible for medical monitoring and treatment as described in 42 CFR 88.1 or 88.12(b).

In addition to 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.

Key Dates

Posted Date

September 03, 2021

Open Date (Earliest Submission Date)

November 1, 2021

Letter of Intent Due Date(s)

November 1, 2021; November 1, 2022; November 1, 2023; November 1, 2024

Application Due Date(s)

December 7, 2021; December 6, 2022; December 5, 2023; December 10, 2024

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

Applicant organizations are strongly encouraged to start the registration process at least 4 weeks prior to the application due date.

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

March 2022; March 2023; March 2024; March 2025

Advisory Council Review

March 2022; March 2023; March 2024; March 2025

Earliest Start Date

July 1, 2022; July 1, 2023; July 1, 2024; July 1, 2025

Expiration Date

December 13, 2024

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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. Funding Opportunity Description

Statutory Authority

The World Trade Center (WTC) Health Program is authorized under the James Zadroga

9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113 and 116–59); codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. §§ 300mm – 300mm–61, 124 Stat. 3623).

Background

The World Trade Center (WTC) Health Program is administered by the National Institute for Occupational Safety and Health (NIOSH). Information on this program is available at the NIOSH 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 Law 116–59. 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 to be conducted under the Zadroga Act includes epidemiologic and other research studies on WTC-related health conditions or emerging conditions among (1) enrolled WTC responders and certified-eligible WTC survivors under treatment; (2) sampled populations outside the NYC disaster area, in Manhattan (as far north as 14th Street) and in Brooklyn; and (3) control populations, to identify potential for long-term adverse health effects in less exposed populations.

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

Purpose

To 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 among enrolled 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.

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 who have been identified as eligible for medical monitoring and treatment as described in 42 CFR 88.1 or 88.12(b).

In addition to 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.

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 wellbeing 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: Project proposals should include discussion describing how research questions, data collection methods and analysis, and dissemination of results will be inclusive of the diversity in the WTC Survivor population, 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.

Applicant research proposals should demonstrate:

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

U01 projects involve longer term research to address critical questions about these, or other, clinical areas.

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.

Translation Research: Projects that evaluate the process whereby existing WTC Health Program research outputs are translated into practical benefits to 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
- Persistent psychiatric conditions such as posttraumatic stress, anxiety and depressive disorders
- Cognitive changes

- Aging – the impacts of aging on those impacted by 9/11 illness and injury (e.g., premature aging, optimizing adaptation for productivity)
- Neurological Diseases
- Aerodigestive health
- Birth and Reproductive Outcomes
- Multisystem or auto-immune diseases
- Emerging conditions – includes diseases/conditions petitioned for consideration to the List of WTC-Related Health Conditions, available at https://www.cdc.gov/wtc/received.html, in the section titled, *Petitions Received and WTC Health Program Responses*.

Objectives

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

- improve diagnosis and treatment activities of the WTC Health Program;
- expand knowledge about health effects related to the September 11, 2001, terrorist attacks;
- answer critical questions about physical and mental health conditions related to the September 11, 2001, terrorist attacks;
- improve the healthcare and wellbeing 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 future disasters (see WTC Health Program Research-to-Care logic model).

Researchers can review WTC Health Program funded projects and publications by visiting the WTC Health Program Research Compendium to assist with an assessment of research gaps/needs.

Another objective of this announcement is to help address the wide range of research needs related to the WTC Health Program. NIOSH will do this by considering the following types of U01 cooperative research projects for 2021 due date/FY2022 funding:

Type of Project	Project Period	Total Cost per Year
Long-Term	Up to four years	Up to $600K
Intermediate-Term	Up to three years	Up to $500K
Short-Term	Up to two years	Up to $350K

A wide range of research needs can be addressed by each type of project. NIOSH anticipates funding 2-8 long-term, intermediate-term, or short-term projects. The project period, budget and anticipated projects to fund may vary in subsequent years of this announcement.

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.

Healthy People 2030 and other National Strategic Priorities

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

Public Health Impact

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

Research to be conducted under the Zadroga Act includes epidemiologic and other research studies on WTC-related health conditions or emerging conditions (1) among enrolled WTC responders and certified-eligible WTC survivors under treatment; and (2) in sampled populations outside the New York City disaster area in Manhattan (as far north as 14th Street) and in Brooklyn, along with (3) 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.

NIOSH's Research Compendium outlines the research goals and accomplishments of the WTC Health Program, program stakeholders, and research grantees. The compendium provides the research mission as defined by the James Zadroga 9/11 Health and Compensation Act of 2010 (Public Law 111–347, as amended by Public Laws 114–113 and 116–59). It gives a brief history of the program, an overview of the research goals, and a bibliography of all WTC Health Program-funded research project publications and links to constituent Primary Investigators and program-related websites and resources.

CDC/NIOSH solicited public comments regarding research priorities for WTC Health Program FY2022 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 at WTC Health Program Research Gateway and 9/11 Health Update (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 Registry's annual reports, prepared for enrollees and the public, include information on its key activities and accomplishments, as well as details on recent findings about the health consequences of 9/11.

The Research-to-Care Logic Model used by the WTC Health Program staff to evaluate the effectiveness of the WTC research program can be found at https://www.cdc.gov/wtc/pdfs/research_to_care.pdf.

More information can be found in the Research Compendium and public comments as described above.

Note: Interested applicants are strongly encouraged to review the Research Compendium, information on current and completed WTC research, and the Registry's annual reports.

Target Population

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

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 who have been identified as eligible for medical monitoring and treatment as described in 42 CFR 88.1 or 88.12(b).

In addition to 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 wellness 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

Mount Sinai School of Medicine

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

Data Requests – Mr. Christopher R. Dasaro, 212-241-1568, christopher.dasaro@mssm.edu

NYC Health and Hospitals Corporation

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

Executive Director – Ms. Angeles Pai, 212-788-3466, paia@nychhc.org

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

WTC Health Registry

Public Affairs Manager – Jacquelynn Osoro, 718-786-4411, josoro@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 WTC Health Program Research-to-Care logic model.

Data/Resource Sharing Plan

NIOSH considers the sharing of unique data and other research resources developed through the WTC Health Program an important means to enhance the value, and further the advancement of, current and future research.

Investigators responding to this funding opportunity should include a plan on sharing research resources and data or explain why such sharing is not possible. The precise content of the plan will vary depending on the data being collected and how the investigator is planning to share the data.

Factors to consider include: the expected schedule for data sharing, the format of the final dataset, supporting documentation, and whether analytic tools will be provided. Other considerations include whether a data sharing agreement will be required, whether any conditions will be placed on their use, and the mode of data sharing.

Information on data/resource sharing can be found on page II-74 (Sharing Research Tools) of the current HHS Grants Policy.

HHS/CDC policy requires that grant award recipients make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication.

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan; Sharing Model Organisms; and Genome Wide Association Studies [GWAS]), as provided in the SF424 (R&R) Application Guide.

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, CDC scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New
Renewal
Resubmission
Revision

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 FOA.

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

An estimate of $12M in total cost (direct and indirect) is available over a 4-year period FY2022-FY2025. NIOSH anticipates funding 2-8 long-term, intermediate-term, or short-term projects.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications. Each year the number of new, renewal and resubmission awards and the total amount awarded will vary, depending on the number of awards that have been completed; the availability of funds; the number and quality of applications; and the duration and cost of the projects proposed. Because the nature and scope of the proposed research will vary from application to application, the size and duration of each award may also vary.

Award Budget

Applicants submitting applications for 2021 due date/FY2022 funding may apply for one of the following: (1) a project period of up to 4 years and a total budget up to $600K per year in direct and indirect costs (total costs); (2) a project period of up to 3 years and a total budget up to $500K per year in direct and indirect costs (total costs); or (3) a project period of up to 2 years and a total budget up to $350K per year in direct and indirect costs

(total costs). The project period and budget vary in subsequent years.

Award Project Period

Allowable project period options are up to 4 years for a long-term project, up to 3 years for an intermediate-term project, or up to 2 years for a short-term project for 2021 due date/FY2022 funding. The allowable project periods vary in subsequent years. Throughout the project period, CDC's commitment to continuation of awards will be conditional on 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.

HHS grants policies as described in the *HHS Grants Policy Statement* will apply to the applications submitted and awards made from this FOA.

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/NIOSH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- 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 apply 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" when submitting via www.grants.gov.

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. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. Click here for more information on FFRDCs.

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 *NIH Grants Policy Statement*, **are not** allowed.

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

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 Dun and Bradstreet Universal Numbering System (DUNS) 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.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- 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.
- o NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but 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 DUNS number and 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.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. All Senior/Key Personnel, including PD(s)/PI(s), must work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. 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.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC/NIOSH 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 FOA does not require cost sharing as defined in the HHS Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. As defined in the HHS Grants Policy Statement, applications received in response to the same Notice of Funding Opportunity Announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit.

CDC/NIOSH will not accept duplicate or highly overlapping applications under review at the same time. 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 NOT-OD-11-101).

In addition, NIOSH will not accept any application in response to this FOA that is essentially the same as one previously reviewed, or as one currently pending initial peer review unless the applicant withdraws the pending application. Resubmission applications may be submitted, according to the Policy on Resubmission Applications from the SF424 (R&R) Application Guide but must include an Introduction addressing the previous peer review critique (Summary Statement).

Responsiveness

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

Applications that exceed the period of performance limit or the total cost per year (including consortium F&A costs) of the proposed project type (long-, intermediate- or short-term) will be considered nonresponsive and will not be reviewed. 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 12 pages for a long-term (up to 4 years) project. Proposals for intermediate-term (up to 3 years) or short-term (up to 2 years) projects shall limit their Research Strategy to 8 pages. These page limits are the totals for 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 list the **Study Design** of your proposed study with a brief description.

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 FOA. If you propose to study FDNY responders, general responders or a combination of WTC responders and survivors, you must submit your applications to the funding announcement PAR-20-280 for funding consideration by the NIOSH WTC Health Program.

You must also include the **primary diseases or conditions** listed in Section I of this announcement (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 **Study Design**, **WTC Subpopulation under study** and **Primary Diseases/Conditions** should be included as one attachment titled "Study Information" in the "12. Other Attachments" section of the "R&R Other Project Information" section of the application. Please note there are other requirements specific to this announcement that must be included in your application: Project Dissemination Plan, Project Evaluation Plan, Resource Sharing Plan and Data Management Plan (see Section IV, 2. Content and Form of Application Submission for information and place to upload the contents), as well as CDC Risk Questionnaire and if applicable, Duplication of Efforts (see Section IV, 7. Other Submission Requirements and Information for instructions).

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

Diseases/Conditions Requiring Further Program Consideration

Applicants may propose to study Other Diseases/Conditions requiring further program consideration. A list of these diseases/conditions is found at https://www.cdc.gov/wtc/received.html, in the section titled, *Petitions Received and WTC Health Program Responses*.

WTC Health Program Reference Documents

The WTC Health Program Research Compendium

NIOSH's Research Compendium outlines the research goals and accomplishments of the WTC Health Program, program stakeholders, and research grantees. The compendium provides the research mission as defined by the James Zadroga 9/11 Health and Compensation Act of 2010. It gives a brief history of the program, an overview of the research goals, and a bibliography of all WTC Health Program-funded research project publications and links to constituent Primary Investigators and program-related websites and resources.

Public Input on the Scope of FY2022 WTC Health Program Research Activities on WTC Survivors

CDC/NIOSH solicited public comments regarding research priorities for WTC Health Program FY2022 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.

Note: Interested applicants are strongly encouraged to review the WTC Health Program Research Compendium, information on current and completed WTC research, and the Registry's annual reports.

Section IV. Application and Submission Information

1. Requesting an Application Package

The SF424 R&R application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

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

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

- E-mail: http://grants.nih.gov/support/index.html.
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.

The NIH eRA Service desk is available Monday-Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the

requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

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

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include both SF424 (R&R) and PHS398 components. These forms can be downloaded from https://grants.nih.gov/grants/forms.htm.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

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 IC 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:

- Descriptive title of proposed activity
- 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:

Michael Goldcamp, PhD
Scientific Review Official
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Telephone: 304-285-5951
Email: MGoldcamp@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:

- the Research Strategy component of the Research Plan is limited to 12 pages for a long-term (up to 4 years) project. Proposals for intermediate-term (up to 3 years) or short-term (up to 2 years) projects shall limit their Research Strategy to 8 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, or 100 pages for all appendices.

Instructions for Application Submission

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

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.

Required Components for this FOA

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

SF424(R&R) Senior/Key Person Profile

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

WTC Health Program Research Meetings

Applicants should anticipate and budget accordingly for a required 2-day meeting for research grantees, held bi-annually in New York City (NYC). These may alternate between webinars and in-person meetings.

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

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with any additional instructions provided in the FOA. The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan. Not all components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed.

Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in this FOA. As applicable to and specified in this FOA, 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 and Revision applications only) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.

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.

Note: Applicants should specify the Study Design, the WTC Subpopulation under study (with description) and include the Primary Diseases/Conditions (with description) listed in the Note to Applicants in Section III of this announcement.

4. Progress Report Publication List (for Renewals only)

Other Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Authentication of Key Biological and/or Chemical Resources

Appendix

12. Appendix

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

Additional Components for this FOA

a. Project Dissemination Plan

b. Project Evaluation Plan

c. Study Design, WTC Subpopulation under study and Primary Diseases/Conditions

> **Please note:** the Project Dissemination Plan and Project Evaluation Plan, as well as study design, WTC Subpopulation under study and Primary Diseases/Conditions (see Note to Applicants in Section III of this announcement) 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: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide. All applications, regardless of the amount of total costs requested for any one year, should address a Data Sharing Plan.

NIOSH considers the sharing of unique data and other research resources developed through the WTC Health Program an important means to enhance the value and further the advancement of current and future research.

Investigators responding to this funding opportunity must include a plan for sharing research resources and data or explain why such sharing is not possible. The precise content of the plan will vary, depending on the data being collected and how the investigator is planning to share the data. Factors to consider include the expected schedule for data sharing, the format of the final dataset, supporting documentation, and whether analytic tools will be provided. Other considerations include whether a data sharing agreement will be required, whether any conditions will be placed on their use, and the mode of data sharing.

Information on data/resource sharing can be found on page II-74 (Sharing Research Tools) of the current HHS Grants Policy.

HHS/CDC policy requires that grant award recipients make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan; Sharing Model Organisms; and Genome Wide Association Studies [GWAS]), as provided in the SF424 (R&R) Application Guide.

Data Management Plan (DMP): 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.

Applicants that plan to collect public health data must submit a 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 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). Other examples of DMPs may be found at USGS.

CDC Additional Requirement (AR)-25 outlines the components of a DMP and provides additional information for investigators about 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 be submitted with the application.

Applications that do not comply with these instructions may be delayed or not accepted for review. Applications submitted without a required DMP may be deemed ineligible for award unless it is clearly stated why a detailed DMP is deferred to a later date and when it will be provided. In these cases, funding restrictions may be imposed on an award until

the DMP is submitted and evaluated.

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 (see "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

Mount Sinai School of Medicine

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

Data Requests – Mr. Christopher R. Dasaro, 212-241-1568, christopher.dasaro@mssm.edu

NYC Health and Hospitals Corporation

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

Executive Director – Ms. Angeles Pai, 212-788-3466, paia@nychhc.org

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

WTC Health Registry

Public Affairs Manager – Jacquelynn Osoro, 718-786-4411, josoro@health.nyc.gov

All instructions in the SF424 (R&R) Application Guide must be followed along with any additional instructions provided in the FOA.

PHS Human Subjects and Clinical Trials Information

Note: The Revised Common Rule defined clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical

or behavioral health-related outcomes. Including behavioral health-related outcomes recognized that clinical trials may occur outside a biomedical context.

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

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

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

Optional Components for this FOA

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

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

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

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

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

register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at 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 DUNS number to the recipient organization.

4. Submission Dates and Times

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

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

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

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date and 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). Errors must be corrected, and a changed/corrected application must be submitted to Grants.gov on or before the

application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

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.

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

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 CDC/NIOSH 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, and embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see 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, recipients 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 FOA.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Awards may be initially issued with restrictions until all information requested can be provided. Generally, funds will not be given for renovation of existing facilities or for purchasing substantial amounts of equipment.

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 this FOA. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this FOA, then you must submit a copy of that questionnaire, or submit a letter signed by the

authorized organization representative to include the original submission date, organization's EIN and DUNS.

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

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, "Required Registrations" 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 PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(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/NIOSH. See Section III of this FOA for information on registration requirements.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

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

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more tips for avoiding common errors and submitting, tracking, and viewing applications:

- https://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- https://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 by the CDC Office of Grants Services (OGS) and responsiveness by OGS and NIOSH. Applications that are incomplete or non-compliant will not be reviewed.

To expedite review, applicants are requested to notify the CDC/NIOSH Scientific Review Official by email at MGoldcamp@cdc.gov when the application has been submitted. Please include the FOA 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, all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system. In addition, as part of the NIOSH mission, all applications submitted to NIOSH in support of occupational safety and health research are evaluated for scientific and technical merit through the NIOSH peer review system.

Overall Impact

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

Scored Review Criteria

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

Significance

Does the project address important needs or critical barriers to help determine physical and mental health conditions which have persisted, and new symptoms and conditions which have emerged, in 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?

For Renewal Applications: Has the project made significant contributions to new knowledge about diseases, conditions, treatments or other areas relevant to community member (survivor) cohorts impacted by the WTC disaster?

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 Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organizational structure appropriate for the project? Do the investigators have a successful track

record in public health research? 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?

For Renewal Applications: Do the investigators have a strong record of research related to the diseases, conditions, treatments or other areas relevant to community member (survivor) cohorts impacted by the WTC disaster?

Innovation

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

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

If the project involves clinical research, are there plans for (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?

Are the overall strategy, methodology, feasibility, and rationale well-reasoned and appropriate to accomplish the specific aims of the project? Does the proposed project timeline include clearly established objectives for which progress will be measured objectively by defined methods? Are potential problems, alternative strategies, and benchmarks for success presented? 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?

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, assure 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 score, but *will not give separate scores* for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the 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 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 or 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.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. 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

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of

the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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.

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 Grantee 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

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.

NIOSH considers the sharing of unique data and other research resources developed through the WTC Health Program an important means to enhance the value and further the advancement of current and future research.

The reasonableness of the resource sharing plan, or the rationale for not sharing research data, will be assessed by the reviewers. The reviewers will not, however, factor the proposed plan into the determination of scientific merit or the impact score.

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

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 announcement 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. Other examples of DMPs may be found at USGS.

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 guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html.

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 submitted in response to this FOA will be evaluated for scientific, technical and educational merit by (an) appropriate Scientific Review Group(s) convened by CDC/NIOSH, in accordance with CDC peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA

Commons.

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.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA.

Following initial peer review, a NIOSH Secondary Review Committee will provide a second level of review for programmatic relevance and balance. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed research 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/resource sharing plan.
- Administrative/managerial capability of the applicant institution.
- Availability of funds.

The NIOSH Secondary Review Committee may review, discuss, prioritize, and recommend applications for funding based on classification of projects by WTC subpopulation(s) and primary diseases or 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 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 Awardee 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. 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 subpart F 45 CFR Part 75 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 application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC/NIOSH will request "just-in-time" information from the applicant as described in the *HHS Grants Policy Statement*.

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 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.

Diversity Supplements: The WTC Health Program and NIOSH support efforts that enhance diversity of the research workforce through recruitment and support for students, post-doctorates, and eligible investigators from diverse backgrounds and groups under-represented in OSH research. To help accomplish this, supplemental funding will be considered after an application is awarded. Please refer to FOA PA-20-222 for information or contact the NIOSH Scientific Program Official (SPO) assigned to this FOA.

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.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please visit here and here for more information.

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 FOA.

- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see link.
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please visit here and here.
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination

against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please visit here and here.

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

Additional Requirements (ARs)

ARs outline the administrative requirements found in 45 CFR Part 75, 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.

Information on additional requirements that apply to this FOA can be found at the following CDC website https://www.cdc.gov/grants/additional-requirements/.

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 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-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: Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-34: Accessibility Provisions and Non-Discrimination Requirements

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 CFR Part 87

Additional Policy Requirements

The following are additional policy requirements relevant to this FOA.

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 website at HHS Policy on Promoting Efficient Spending.

Federal Funding Accountability and Transparency Act of 2006

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, http://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://plainlanguage.gov/law/.

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all recipients to implement the following optional evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.

Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.

Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

https://www.gsa.gov/cdnstatic/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

https://www.cdc.gov/nccdphp/dnpao/

https://www.cdc.gov/obesity/strategies/food-serv-guide.html

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

Pilot Program for Enhancement of Employee Whistleblower Protections

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

Copyright Interests Provision

This provision is intended to ensure that the public has access to the results and

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

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

Language Access for Persons with Limited English Proficiency

Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see here and LEP website. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care here.

Dual Use Research of Concern

On September 24, 2014, the US Government Policy (USG) 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 https://www.phe.gov/s3/dualuse/Pages/default.aspx.

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.

Federal Information Security Management Act

All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIOSH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIOSH recipient applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The recipient retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. When information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

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 Additional Requirement 36 to ensure compliance with this term and condition.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when state and local governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an “assistance” mechanism (rather than an “acquisition” mechanism), in which substantial CDC programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients’ activities by involvement and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

The PDs/PIs will have primary responsibility for the following:

- Designing and conducting research to address the described research objectives of this cooperative agreement
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support detailing the nature and extent of involvement or memoranda of understanding.
- Establishing goals and objectives that are realistic, measurable, and time-oriented for all phases of the project
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable
- Collaborating with CDC in design and implementation of research and the analysis, interpretation, and dissemination of study findings
- Developing, designing, and piloting research protocols and instruments; recruiting participants according to the defined sampling strategy; and conducting appropriate data management procedures
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings
- Attending and participating in bi-annual grantee research meetings.

Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to government rights of access consistent with current HHS, PHS, and CDC policies.

NIOSH staff with relevant subject matter expertise may have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. These include, but are not limited to, these activities:

- Assisting in review of research protocols (such as for sampling, recruitment, assessment, and data management)
- Advising on or participating in analysis, interpretation, and dissemination of study findings
- Attending and participating in bi-annual grantee meetings
- Monitoring and evaluating the scientific and operational accomplishments of the project through conference calls, site visits, grantee meetings, and review of technical reports.

Specific substantial involvement activities for NIOSH project scientists will be negotiated further with each recipient as part of the pre-award process. This will include adding special terms and conditions in the NOA.

NIOSH Program Official (PO)

Additionally, the Scientific/Research Contact named in this announcement will serve as the Program Official (PO) for all awards. This person will be responsible for the normal scientific and programmatic stewardship of these awards and will be named in the NOAs. The PO will have programmatic involvement during the conduct of this activity through approval of progress reports, human subjects protection, and advice and coordination commensurate with normal program stewardship for grants. Other PO responsibilities include these:

- Ensuring that all requirements are met prior to issuance of an initial award
- Objective and independent evaluation of progress toward specific aims or objectives

- Approving noncompetitive continuation of the award
- Recommending corrective actions as needed
- Carrying out administrative and technical duties such as giving grant cycle or funding information, programmatic approvals and recommendations, consultation or technical assistance pertaining to administration requirements of award; monitoring performance of the recipient; processing "just in time" information for research projects; approving final reports before release and distribution; communicating guidance and policy; facilitating budget recommendations; visiting programs/sites; attending grantee meetings; and disseminating recipient information and research reports
- Providing guidance or information addressing recipient inquiries
- Participate in and facilitate development of goals and agenda for grantee meetings, as necessary.

Areas of Joint Responsibility

Responsibilities are divided between recipients and NIOSH staff as described above. Substantial involvement responsibilities of NIOSH project scientists will be collaborative, consultative, and facilitative, not proscriptive, in nature.

Dispute Resolution

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and NIOSH may be brought to Dispute Resolution. A Dispute Resolution Panel will be convened and will have three members: a designee of the recipient, a NIOSH designee, and a designee with expertise in the relevant area who is chosen by the other two. This special dispute resolution procedure does not alter the recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D, and HHS regulations 45 CFR Part 16.

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. Program staff will evaluate the effectiveness of resource sharing as part of the administrative review of each Non-Competing Continuation Grant Progress Report.

A final progress report, invention statement, 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. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) on all subawards over $25,000. See the HHS Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period.

The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

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

1. Yearly Non-Competing Grant Progress Report. The RPPR is due 90 to 120 days prior to the end of the current budget period and 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 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends.

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

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 scientific findings be translated into public health practice or inform public health policy?

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

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

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

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

How will this project lead to improvements in public health?

How will the findings, results, or recommendations been used to influence practices, procedures,

methodologies, etc.?

How will the findings, results, or recommendations 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 eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

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

The due date for final FFRs will continue to be 90 days after the Period of Performance end date.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and

accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at NIH Forms Library. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page.

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

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

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 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 and annual outcome update is available on the NIOSH OEP website under Grant Closeout.

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

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post-submission issues, FFR submission)

Finding Help Online: http://grants.nih.gov/support/ (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

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

Peer Review Contact
Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Michael Goldcamp, PhD
Scientific Review Official
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Telephone: 304-285-5951
Email: MGoldcamp@cdc.gov

Financial/Grants Management Contact
LaQuanda Lewis, MPH
Grants Management Specialist
Office of Grants Services (OGS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-2969
Email: hrf6@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.
Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 U.S.C. 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations. Awards are made under the authorization of the 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 and 116–59; codified in Title XXXIII of the Public Health Service Act at 42 U.S.C. §§ 300mm – 300mm–61, 124 Stat. 3623). All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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