Centers for Disease Control and Prevention

NIOSH - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Continuation and Expansion of the National Mesothelioma Virtual Bank for Translational Research (U24)

RFA-OH-21-007

03/25/2021

Table of Contents

Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Institute for Occupational Safety and Health

Notice of Funding Opportunity (NOFO) Title

Continuation and Expansion of the National Mesothelioma Virtual Bank for Translational Research (U24)

Activity Code

Cooperative Agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-OH-21-007

Assistance Listings (CFDA) Number(s)

93.262

Category of Funding Activity

HL - Health

NOFO Purpose

The National Mesothelioma Virtual Bank for Translational Research (NMVB) was established in 2006 to serve as an exceptional resource for malignant mesothelioma research. The purpose of this Notice of Funding Opportunity (NOFO) is to continue to advance biomedical research for malignant mesothelioma by expanding the collection of biospecimens, related data, and other information in the NMVB. The NMVB is capable of providing biospecimens (such as fresh frozen tumor and control tissues, paraffin embedded tissues, and blood and DNA samples from

mesothelioma patients), together with demographic data (age, sex, race, occupational history and other epidemiologic information), and clinical data (stage, treatment and survival information). Additionally, the virtual registry and tissue bank serves as a virtual repository and offers a library of reagents and data (such as genomic, transcriptomic and proteomic data) for sharing among investigators.

The NMVB may assist in the identification and development of early markers of disease, biomarkers of stage and prognosis, as well as new or improved treatment modalities. It does so by allowing access to biospecimens for research on biomarkers in early detection of malignant mesothelioma, susceptibility, epidemiologic characteristics (such as occupational history and death certificate information), and clinical factors (such as improvements in prognosis as a result of improvements in treatment). Through this NOFO, the awardee will continue to expand the NMVB, improving its capability to serve as a resource for biomedical researchers and the clinical science community focused on malignant mesothelioma.

A virtual registry and tissue bank are comprised of participating institutions that share their independent banking collections of tissues and relevant information for use by the research community through a centralized network of collaborators in the registry. This registry is used for data recording and collection related to each tissue sample. Each participating institution is responsible for entering data and updates into the registry for their samples, however, each uses common data elements and state-of-the-art security for protection of sensitive or personally identifiable data, as appropriate.

The recipient who enters into this cooperative agreement will continue to manage and further enhance the development and utility of the NMVB for expanded use by the biomedical research community, which may lead to improved health outcomes for mesothelioma patients.

Key Dates

Publication Date:
To receive notification of any changes to RFA-OH-21-007, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
02/25/2021

Application Due Date:
03/25/2021
On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore

identifying issues earlier in the application submission process.

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

Scientific Merit Review:
05/11/2021

Secondary Review:
06/10/2021

Estimated Start Date:
09/01/2021

Expiration Date:
10/01/2021

Due Dates for E.O. 12372:
Executive Order 12372 does not apply to this program.

Required Application Instructions

Applicants must use ASSIST at https://public.era.nih.gov/assist to prepare and submit applications electronically through Grants.gov to CDC. ASSIST provides many features to facilitate the application submission process which improves data quality (e.g. pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review).

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 12 pages.

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

Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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

Executive Summary

- **Purpose.** The National Institute for Occupational Safety and Health (NIOSH) announces the availability of funds to support one cooperative agreement (U24) for continuation and expansion of the National Mesothelioma Virtual Bank for Translational Research

(NMVB). The purpose of the virtual mesothelioma registry and tissue bank is to provide a resource for investigators engaged in mesothelioma research.

- **Mechanism of Support.** Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards.** NIOSH anticipates that up to $1,100,000 will be available in FY 2021, and that one award will be made under this NOFO. The award issued under this NOFO is contingent upon availability of funds.
- **Budget and Period of Performance.** The estimated total funding (direct and indirect costs) for the first year (12-month budget period) is up to $1,100,000. The estimated total funding (direct and indirect costs) for the entire project period (09/01/2021 - 08/31/2026) is up to $5,500,000.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 are eligible to apply. For this NOFO, CDC has approved a single eligible institution.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources at the University of Pittsburgh (PA) necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Multiple PDs/PIs are allowed.
- **Number of Applications.** One application is expected. See Section III. Eligibility.
- **Application Type.** Renewal and Revision applications will be accepted.
- **Special Date(s).** Not Applicable.
- **Application Materials.** See **Section IV.1** for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Section I. Funding Opportunity Description

Statutory Authority

This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review. Awards are made under the authorization of the Occupational Safety and Health Act of 1970, Section 20(a) and 21(a) (29 USC 669(a) and 29 USC 670); Federal Mine Safety and Health Act, Section 501(a), 30 USC 1 (Note), and 30 USC 951(a); and Section 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52. All awards are subject to 45 CFR Part 75, the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

1. Background and Purpose

Background

Malignant mesothelioma is a neoplasm associated with occupational and environmental inhalation exposure to asbestos fibers and other elongated mineral particles (NIOSH, 2011; NIOSH, 2017). This rare form of cancer usually affects the sac lining (mesothelium) of the chest

(the pleura), the abdominal cavity (the peritoneum), or the lining around the heart (the pericardium). Because asbestos mineral fibers are flame and heat resistant, pliable, strong, refractory to corrosive chemicals, and provide insulation (https://www.cdc.gov/niosh/topics/asbestos/default.html), asbestos has been used to insulate buildings from heat and to protect against fire (especially important in the shipbuilding industry), in fabric for protective suits, as a brake liner (e.g., automobiles and railroad rolling stock), for engine gaskets, and for making filters (e.g., in the chemical industry). Thus, Americans have been exposed to asbestos in the workplace since its use became widespread in the mid- to late-nineteenth century.

About 125 million people in the world are exposed to asbestos at the workplace. During 1999 – 2015, a total of 45,221 deaths with malignant mesothelioma mentioned on the death certificate as the underlying or contributing cause of death were reported in the United States (NIOSH, 2017). Hazardous occupational exposures to asbestos fibers have occurred in industrial operations including mining and milling, manufacturing, shipbuilding and repair, and construction (NIOSH, 2011; NIOSH, 2017). Current exposures to commercial asbestos in the United States occur predominantly during maintenance operations and remediation of older buildings containing asbestos (NIOSH, 2011; NIOSH, 2017). The latency period from first causative exposure to malignant mesothelioma development typically ranges from 20 to 40 years, but can be as long as 71 years (NIOSH, 2011; NIOSH, 2017). Because of the latency period for malignant mesothelioma, most individuals are older when they are diagnosed.

The projected number of malignant mesothelioma deaths was expected to increase to 3,060 annually by 2001-2005, and after 2005, mortality was projected to decrease. During 1999-2015, the annual number of malignant mesothelioma deaths increased 4.3% overall, from 2,479 in 1999 to 2,579 in 2015 (NIOSH, 2017). Contrary to past projections, the number of malignant mesothelioma deaths has been increasing, thus malignant mesothelioma continues to be an ongoing and significant public health problem in the United States.

Numerous factors affect the prognosis and treatment options for individuals with malignant mesothelioma. Diagnosis of malignant mesothelioma can be difficult, but early detection is critical for improved health outcomes. In addition, treatment is difficult and may include surgery, radiation, chemotherapy, biologic therapy, or clinical trials. Improvement of malignant mesothelioma diagnosis and treatment options depends on continuation of enhanced, diverse research. Discovery of more biomarkers for early detection, better understanding of the disease progression, and development of more effective treatments are needed to combat this deadly disease.

Purpose

The National Mesothelioma Virtual Bank for Translational Research (NMVB) was established in 2006 to serve as an exceptional resource for malignant mesothelioma research purposes. Published information on the NMVB is available at https://mesotissue.org/publications/. The purpose of this NOFO is to continue to advance biomedical research for malignant mesothelioma by expanding the collection of biospecimens, related data, and other information in the NMVB. The NMVB is capable of providing biospecimens (such as fresh frozen tumor and control tissues, paraffin-embedded tissues, and blood and DNA samples from mesothelioma patients),

together with demographic data (age, sex, race, occupational history and other epidemiologic information), and clinical data (stage, treatment and survival information). Additionally, the registry/tissue bank serves as a virtual repository and offers a library of reagents and data (such as genomic, transcriptomic, and proteomic data) for sharing among investigators. The NMVB may assist in identification and development of early markers of disease, biomarkers of stage and prognosis, as well as new or improved treatment modalities by allowing access to biospecimens for research on biomarkers for early detection of malignant mesothelioma, susceptibility, epidemiologic characteristics (such as occupational history and death certificate information), and clinical features (such as improvements in prognosis due to improvements in treatment). Through this funding, the awardee will continue to expand the NMVB, improving its capability to serve as a resource for biomedical research and the clinical science community focused on malignant mesothelioma.

A virtual registry and tissue bank is comprised of participating institutions that make their independent banking collections of tissue and relevant information available for use by the research community through a centralized virtual network of collaborators in the registry. This registry is used for data recording and collection related to each tissue sample. Each participating institution is responsible for entering the data and updates into the registry for their samples. However, participants use common data elements and state-of-the-art cybersecurity for protection of sensitive or personally identifiable data. The funding recipient entering into this cooperative agreement will manage and further enhance the development and utility of the NMVB for expanded use by the biomedical research community, which may lead to improved health outcomes for patients with malignant mesothelioma.

Healthy People 2030 and other National Strategic Priorities

The United States Public Health Service (PHS) is committed to achieving nationwide improvements in health for a society in which all people live long, healthy lives. The vision, mission, and goals are found in Healthy People 2020. The objectives of Healthy People 2020 related to occupational safety and health (OSH) are primarily addressed through the National Occupational Research Agenda (NORA). NORA, established by NIOSH and its partners to stimulate research and improve workplace practices, provides a framework to guide OSH research.

The Centers for Disease Control and Prevention and NIOSH support the Healthy People 2020 goal to reduce the overall cancer death rate. This NOFO contributes to this goal by aiming to reduce the number of new cancer cases, as well as the illness, disability, and death caused by malignant mesothelioma. The NMVB aids in the overall scientific advancement and goal of reducing the number of new malignant mesothelioma cases and improving overall health outcomes for individuals with this disease.

Looking forward, Healthy People 2030 is the fifth edition of Healthy People. It aims at new challenges and builds on lessons learned from its first 4 decades. HHS has approved the Healthy People 2030 framework, which is based on recommendations made by the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030.

Public Health Impact

Public health impacts include the development of innovative plans to promote the benefits and uniqueness of the NMVB; the usefulness of NMVB to the scientific community in the conduct of research studies that address the etiology, mechanisms, diagnosis and treatment of malignant mesothelioma; the evaluation of diagnostic and prognostic markers from malignant mesothelioma tissue with associated clinical and outcome data; and the potential for improving the overall quality of life of current and former workers diagnosed with and treated for malignant mesothelioma, which is often fatal.

Relevant Work

NIOSH has provided financial, scientific and technical assistance for the creation, expansion, growth, and maintenance of infrastructure and staffing for the NMVB at the University of Pittsburgh since 2006. Under the terms of a cooperative agreement, NIOSH personnel serve on the Steering Committee and provide expertise and support to the NMVB. It is the intention of this NOFO to continue NIOSH's support of the virtual bank which has already supported many research studies and publications about malignant mesothelioma (https://mesotissue.org/).

2. Approach

The objectives of the NMVB are as follows:

- Continue to expand the NMVB (for example, increase clinical resources and data). By seeking new collaborations with other institutions and organizations, the recipient will enroll increasing numbers of mesothelioma patients to become participants in the virtual registry and tissue bank. Participating institutions will identify and enroll mesothelioma patients at their institutions. The NMVB will expand the collection of patients' clinical and demographic data (retrospective and prospective), including data determined to be necessary for diagnosis and inclusion in the registry and tissue bank, as well as biological samples including (but not limited to) biopsy and surgical material (fixed or frozen) and whole blood components. The recipient of this award will continue to establish and improve standards for participants to post clinical data, demographic data, occupational history, and available samples in a distributed network allowing databases of individual participating institutions to be accessed together, forming a single virtual database. The NMVB will ensure that all participating institutions maintain appropriate Institutional Review Board (IRB) approvals, state-of-the-art data safety and protections, quality assurances and quality controls for biospecimens and related data, and continued efforts to promote and enhance electronic medical records.
- Promote the mesothelioma patient registry and tissue bank as a resource for the clinical science community. The recipient, together with participating institutions, will maintain a process for qualified applicants to access information in the database and to request available samples for use in legitimate research. Together with NIOSH, the recipient will continue to expand and improve the marketing of the availability and utility of the NMVB as a resource to prospective users, including the research community and public, using information obtained by this tracking documentation. The recipient will work with existing mesothelioma tissue and data banks, and develop innovative plans to promote the benefits and uniqueness of the virtual registry and bank for mesothelioma research.
- Document the usefulness of the NMVB to the scientific community in the conduct of studies that address the etiology, mechanisms, diagnosis and treatment of malignant mesothelioma. The recipient will maintain a record of requests for access to the database;

requests for use of tissue samples; tissue samples distributed; and scientific abstracts, presentations, and publications resulting from use of the registry and tissue bank.

These are the anticipated potential outcomes:

- Evidence of grant support (Federal or non-Federal) obtained by mesothelioma researchers subsequent to using NMVB resources.
- Patents or clinical diagnostic or therapeutic products resulting from use of the NMVB.
- Improved patient outcomes in the long-term.

Proposed goals and objectives should be clearly stated in the application and directly linked to the occupational health and safety burdens being addressed. Applicants are expected to justify their proposal by describing the burden of the problem, the need for the proposed research or activity, and the potential for impact or likelihood of success.

Applicants should provide data to support their selection of proposed work, such as morbidity or mortality rates, indicators of the size of the population at risk including estimates of the target population's potential risk of exposure to the hazard, frequency of exposure, or sociodemographic factors such as age, gender, and race/ethnicity. Similarly, applicants may provide qualitative data and/or information that describe exposures, the magnitude of the problem, and potential benefits and impacts of addressing the issue. Qualitative data and/or information may be necessary when the nature of the exposure or population at risk makes collecting large-scale, representative quantitative data difficult.

Data Resources:

Specific information about malignant mesothelioma can be obtained at the NIOSH Malignant Mesothelioma Mortality Data.

In addition, NIOSH has a number of data resources available to researchers on the NIOSH Data and Statistics Gateway. This includes Worker Health Charts that use worker health data gathered by NIOSH from the Bureau of Labor Statistics to create specialized charts to assess the rates, distribution, and trends in workplace injuries, illnesses and deaths.

Objectives/Outcomes

Objectives

Proposed goals and objectives should be clearly stated in the application and directly linked to the occupational safety and health burdens being addressed. Applicants are expected to justify their proposal by describing the burden of the problem, the need for the proposed research or activity, and the potential for impact or likelihood of success. Provide data to support your selection of the proposed work, such as morbidity or mortality rates and indicators of the size of the population at risk (including estimates of the target population’s potential risk of exposure to the hazard, frequency of exposure, or sociodemographic factors such as age, gender, and race/ethnicity). Similarly, provide qualitative data that describe exposures, the magnitude of the problem, and potential benefits and impacts of addressing the issue. Qualitative data may be necessary when the nature of the exposure or population at risk makes it difficult to collect large-scale, representative quantitative data.

Outputs and Outcomes
Governmental agencies and organizations have been faced with increasing demand to measure the effectiveness of their funded research in improving public health. Effectiveness can be measured by the products (outputs) of research activities and subsequent outcomes, that is, benefits or changes at an individual or population level.

Outputs are the immediate products or direct result of research activities. Examples include publications, reports, conference proceedings, presentations/posters, investigator career development, databases, tools, methods, guidelines, recommendations, and education and training materials. The causes of work-related injuries and illnesses are complex and determining the effect that specific research activities have on them can take years. Thus, ***outcomes*** can be measured over time as either ***intermediate*** or ***end outcomes.***

Intermediate outcomes are specific changes that occur as a result of research activities. Examples of intermediate outcomes include public or private policy changes, conduct of training or workshops based on project outputs, citations in the literature, inventions and patents, and adoption of technologies or methods developed by the researcher.

End outcomes are the ultimate goal of the research and the result of what individuals or institutions do with the knowledge or products generated by the research. Examples of end outcomes include reduction in workplace illnesses, injuries, fatalities, and/or hazardous exposures.

Note to Applicants:
In the Project Description/Abstract and Research Strategy (Significance) sections of your application, provide a brief statement about expected outputs and outcomes of your proposed research.

Target Population
Through support of expansion and maintenance of the NMVB, this announcement indirectly supports development of potential diagnostics and treatments and improved health outcomes for current or former workers and others with mesothelioma.

Collaboration/Partnerships
This NOFO continues ongoing support for the NMVB and its partnerships, comprised of a consortium of academic and biomedical organizations involved in clinical care for and biomedical research on malignant mesothelioma.

Partnerships are important for the NMVB. They facilitate advances in the safety and health of U.S. industry workers. Input from industry and stakeholder groups, which have inherent knowledge and concern about the safety and health of industry workers, as it relates to mesothelioma, will enhance research projects. Partners often add expertise or specialized experience to the research team, which contributes to the success of the overall project.

The applicant will institute collaborative partnerships with local and state organizations, universities, manufacturers, government agencies, professional organizations, engineering and

safety training partner organizations, community organizations, health care institutions, business groups, and labor organizations to carry out the proposed researched activities.

Partnerships are also critical to translate research findings into effective training and work practices and are encouraged by the NIOSH Research-to-Practice Program (r2p). Interdisciplinary and transdisciplinary collaborations that share expertise are essential to advancing occupational safety and health, and promoting overall worker safety among industry workers.

Note to Applicants:
Include collaborations or partnerships that strengthen the proposed research in terms of OSH, or related expertise and resources.

Evaluation/Performance Measurement
Evaluations provide information for management and improve program effectiveness. The following CDC document, A Framework for Program Evaluation, may 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.

The applicant will provide a description of the usefulness or utility of the NMVB, using a number of indicators and qualitative and quantitative measures. Performance elements include components listed in the Objectives section, such as increasing numbers of malignant mesothelioma-related specimens and data, publications, presentations, and patents. Evidence of grant support (Federal or non-Federal) obtained by non-NMVB cancer researchers after using resources obtained from the NMVB will be considered a long-term potential outcome of this work.

Translation Plan
In addition to NORA, NIOSH has established a Research-to-Practice (r2p) program. The r2p approach is an interactive process in which the occupational safety and health community, which includes researchers, communicators, decision-makers, and employer/employee groups, work collaboratively to:

- Identify research needs;
- Design, plan, and conduct studies;
- Translate and disseminate existing knowledge, interventions, and technologies to relevant users for implementation in the workplace; and to
- Evaluate results to determine the impact on occupational safety and health.

The applicant will describe the anticipated strategies for translation and/or dissemination of research findings, including by audience segmentation and by the characteristics of the channels or modes of dissemination.

Section II. Award Information

Funding Instrument Type:

CA (Cooperative Agreement)
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:
Renewal (formerly Competing Continuation) - Previous years of funding for the project have elapsed. Competing for additional years of funding to continue original project.
Resubmission (formerly Revision or Amended Application) - For NOFOs that with multiple receipt dates. Application previously reviewed. A revised or amended application addresses reviewer feedback.
Revision (formerly Competing Supplement) - Request for additional funds for a current award to expand the scope of work. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Estimated Total Funding:
$ 5,500,000
This award will support up to $1.1 million in total costs (direct and indirect) for the first 12-month budget period and up to $5.5 million in estimated total costs (direct and indirect) for one award for the entire 5-year period of performance.

Anticipated Number of Awards:
1
This award will support up to $1.1 million in total funding (direct and indirect) for the first 12-month budget period and up to $5.5 million estimated total funding (direct and indirect) for one award for the entire 5-year period of performance.

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

Award Ceiling:
$ 1,100,000
Per Budget Period

Award Floor:
$ 750,000
Per Budget Period

Total Period of Performance Length:
5 year(s)

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

interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

3. Additional Information on Eligibility

This is a single-eligibility award. Only the University of Pittsburgh, the institution with the existing National Mesothelioma Virtual Bank for Translational Research, is eligible to apply.

The applicant institution **must** have an established registry and tissue bank with the capability of functioning as a national virtual registry and tissue bank for mesothelioma, one in which participating institutions will make available their independent stores of mesothelioma tissue for public access and use through a centralized Internet-based database or registry. This virtual registry and tissue bank must be able to provide a resource for investigators engaged in the research of mesothelioma, to include, but not limited to, biospecimens (blood, plasma, white blood cells, and normal and malignant mesothelioma tissues) together with demographic data such as age, sex, race, occupational history and other epidemiologic information, and clinical data (stage, treatment and survival information).

4. Justification for Less than Maximum Competition

A Single Source Justification (SSJ) was approved by the CDC on November 10, 2020. Under the provisions of the SSJ, only the University of Pittsburgh, which manages the existing National Mesothelioma Virtual Bank, is eligible to apply. The University of Pittsburgh is uniquely qualified to perform the programmatic activities identified in this NOFO for the following reasons:

- The NMVB was established at the University of Pittsburgh using a competitive grant application and review process in 2006, and has been the sole recipient of this funding to date. During its 14 years of funding, the University of Pittsburgh has grown and expanded the virtual bank and its partnerships under the cooperative agreement with NIOSH.
- The NMVB is now the largest mesothelioma biospecimen resource in the country and is comprised of five healthcare academic collection sites: The University of Pittsburgh Medical Center, New York University, the University of Pennsylvania, Roswell Park Cancer Institute, and the University of Maryland Medical Center. Under the guidance of NIOSH, the NMVB continues to reach out to new potential partners and researchers.
- Since its inception, the NMVB has been accumulating and providing researchers with biospecimens (such as fresh frozen tumor and control tissues, paraffin-embedded tissues, and blood and DNA samples from mesothelioma patients), together with demographic

data (age, sex, race, occupational history and other epidemiologic information), and clinical data (stage, treatment and survival information). As a virtual repository, the NMVB offers a library of reagents and data (such as genomic, transcriptomic, and proteomic data) for sharing among investigators focused on mesothelioma. These resources are essential for the identification and development of early markers of disease, biomarkers of stage and prognosis, as well as new or improved treatment modalities. Ultimately, the NMVB facilitates the understanding of the mesothelioma disease process by providing researchers access to biospecimens for research.

5. Responsiveness

The applicant **must** provide evidence of an existing mesothelioma registry and virtual tissue bank in order to be eligible for applying to this announcement. The application will be considered nonresponsive if it does not demonstrate these capabilities.

If the applicant exceeds the five-year period of performance limit or the total cost limit of $1,100,000 per budget period (including consortium F&A costs), CDC/NIOSH will consider the application non-responsive, and it will not enter the peer review process. CDC/NIOSH will notify the applicant that the application did not meet the submission requirements.

Upon receipt, the application will be evaluated for completeness by the CDC Office of Grants Services (OGS), and responsiveness by OGS, and the Center, Institute, or Office of the CDC. Incomplete and/or non-responsive applications will not be reviewed.

Note to Applicant:
Provide a statement about which NORA sector(s) and cross-sector(s), and which NIOSH strategic and intermediate goals are being addressed. Provide a rationale for how the proposed research will contribute to the specified priority area(s). Explain how the proposed research will contribute to the NIOSH Research to Practice (r2p) initiative and state the expected Outcomes and Outputs (see Approach). Place this information in both the Project Abstract and in the Research Strategy (Significance) sections of the application.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

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

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

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

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

Additionally, all applicant organizations must register in the **System for Award Management (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 https://www.sam.gov/index.html.

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

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and

ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement,(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to thisNOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

- E-mail: http://grants.nih.gov/support/index.html
- 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 instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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

3. Letter of Intent

The LOI date will generate once the Synopsis is published if Days or a Date are entered. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan the review. By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

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

The letter of intent should be sent to:
Michael Goldcamp, Ph.D.
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 304-285-5951
Email: MGoldcamp@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

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

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.

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

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

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

Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Instructions for Application Submission:
The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this NOFO.

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.
List all performance sites that apply to the specific project.

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 NOFO, CDC/NIOSH requires a detailed budget for the initial budget year and a budget for each consecutive year of support. Modular budgets are not allowed.

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

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

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:
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, with the following modifications: All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Examples of DMPs may be found at University of California (https://cdlib.org/services/uc3/dmptool/).

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

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

Study Record: **PHS Human Subjects and Clinical Trials Information**
All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study
Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).
All instructions in the SF424 (R&R) Application Guide must be followed.
.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 100 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

9. Submission Dates & Times

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

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

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

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

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

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

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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

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

a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 03/25/2021

03/25/2021
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

11. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.

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

Protecting Life in Global Health Assistance:

In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability(https://www.cdc.gov/grants/additional-requirements/ar-35.html).

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of

generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

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

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

Human Subjects:

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

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

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

Pre-award costs are not allowed.

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

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

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

Duplication of Efforts

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

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

Application Submission

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

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

For assistance with your electronic application or for more information on the electronic

submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

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

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

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

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

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

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

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to

be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance **Maximum Points:** 0

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Does the proposed research further develop the concept and usefulness of the mesothelioma virtual registry and tissue bank? Will the proposed research further enhance access of the clinical science community to mesothelioma tissue and data resources? For Renewal applications, is there sufficient information provided describing how the NMVB has achieved the goals from the previous funding period and how the goals of the future years will build on the past successes? Is there a plan for expanded interactions with other institutions and organizations for enhancement of the existing NMVB?

In addition, for applications proposing clinical trials:

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

Investigator(s) **Maximum Points:** 0

Are the PD/PIs, collaborators, and other researchers well-suited for the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

For Renewal applications, have the Principal Investigator and team of collaborators demonstrated active engagement and are they highly motivated for the success of the NMVB?

In addition, for applications proposing clinical trials:

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

Innovation **Maximum Points:** 0

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 PI describe how the enhanced NMVB for Translational Research will serve as a unique resource for researchers in this field and how the research team will collaborate with other related resources to further enhance the utility of the virtual registry and tissue bank?

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 **Maximum Points:** 0

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and how will particularly risky aspects be managed? If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Does the application describe approaches and goals for how the results will be presented for various audiences and be disseminated and ultimately used? Does the application address research translation and describe how the resource will contribute to the overall mesothelioma clinical and research community? Does the project have a well-developed and well-conceived evaluation plan? Are outputs identified and are the measures/metrics to assess outcomes included? For Renewal applications, has the progress made in the last funding period been well-described and is there evidence of past successes? Has the applicant documented outcomes and impacts that have been achieved in the previous funding period?

In addition, for applications proposing clinical trials:

Does the application adequately address the following, if applicable?

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver

interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

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

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

Data Management and Statistical Analyses

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 **Maximum Points:** 0

Will the scientific environment where the research will be conducted 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?

Is the collaborative effort of the participating institutions/organizations likely to continually increase and improve the NMVB? Does the applicant provide evidence of existing systems and/or infrastructure that are critical to the success of the proposal? Does the applicant have an existing NMVB for Translational Research or other actual or virtual registry and tissue bank? Has the applicant addressed how it will work with the existing registry and bank to maintain, enhance and improve the bank through this cooperative agreement?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

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

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

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

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of

Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

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

3. Additional Review Considerations

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

Confidentiality

Because of the sensitive nature of an Internet-based registry, applicants need to specifically address how confidentiality issues will be handled in the reporting and use of data from the Internet-based registry. Does the applicant describe the type of information that will be collected related to the tissues and other biospecimens included in the virtual registry and bank, and how this information will be used and protected?

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

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

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

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

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

- 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.

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

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

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

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

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

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

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

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

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

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

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-7: Executive Order 12372 Review
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-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR-31: Research Definition
AR-32: Appropriations Act, General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-36: Certificates of Confidentiality

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

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

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

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will

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

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

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

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

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

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

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

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

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

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

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (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 recipient's activities by involvement in and otherwise working jointly with the award recipient in a partnership role; CDC Project Officers are 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 recipient for the project as a whole, although specific tasks and activities may be shared among the recipient and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.
- Coordinating project activities technically, scientifically, and administratively at the awarded institution, and at other sites that may be supported by this award.
- Defining objectives and approaches; collecting and analyzing data; and publishing results, interpretations, and conclusions of studies conducted under the terms and conditions of the program award.
- Expanding and enhancing the mesothelioma virtual registry and tissue bank.
- Ensuring that appropriate Institutional Review Board approvals for research involving human subjects for all participating sites, collaborators, or partners are obtained.
- Retaining custody of, and primary rights to, the data and software developed under this award, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Establishing a Coordinating/Steering Committee in accordance with Section 2.A.3.
- Organizing an annual Face-to-Face meeting of the Coordinating/Steering Committee.
- Publicizing the availability of the virtual registry and tissue bank.
- Consulting with CDC/NIOSH to ensure compliance with relevant grant policies and regulations.

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

• Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html

CDC/NIOSH anticipates having substantial scientific involvement during the conduct of this activity in the form of technical assistance, collaboration, guidance, and coordination. A CDC/NIOSH Project Scientist may be involved and, if so, will have responsibilities that include the following:

- Serve as subject matter expert for mesothelioma, registries, and tissue banking.
- Attend and actively participate in the Coordinating/Steering Committee meetings.
- Publish with the grantee in accordance with HHS, CDC, and NIOSH publication policies.
- Assist in the dissemination of research results.
- Participate in Coordinating/Steering Committee meetings (as voting member).
- Facilitate coordination and collaboration on specific aims, goals, meeting agendas, and registries development.

The NIOSH Project Scientist/Collaborator will work closely with the CDC/NIOSH Program Official.

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 DHHS, PHS, and CDC policies.

Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The program official will have the following duties:

- Provide objective and independent evaluation of progress toward specific aims or objectives.
- Coordinate with grantee to ensure that complete and sufficient information is provided prior to any award action.
- Review and approve progress reports.
- Approve non-competitive continuation of the award.
- Provide guidance on grant policies and regulations.
- Recommend corrective actions as needed.
- Provide guidance or information for addressing recipient inquiries.
- Participate in Coordinating/Steering Committee meetings (as non-voting member).
- Approve annual report.
- Facilitate goals and agenda for Coordinating/Steering Committee meetings, as appropriate.

Areas of Joint Responsibility include:

Coordinating/Steering Committee

- The awardee will manage the NMVB with collaboration, consultation, and guidance from CDC/NIOSH. A Coordinating/Steering Committee will be established by the recipient

and will consist of (1) the Principal Investigators; (2) representatives from the awardee institution; (3) members from each tissue/data accruing site; (4) a patient advocate; (5) the NIOSH Program Official; and (6) the NIOSH Project Scientist. Additional members may be added by majority approval.

- The Coordinating/Steering Committee will help guide activities undertaken by the NMVB. This will include ensuring (1) proper operating policies; (2) a manual of standard operations for procedures to access, process and distribute tissue; (3) uniform quality control methods; (4) rules for access to the clinical and outcome data associated with the accrued cases; and (5) maintenance of adequate security and confidentiality. An annual Face-to-Face meeting of the Coordinating/Steering Committee will be held to discuss progress, important findings, and challenges. These meetings will also provide an opportunity for critical discussions on enhancing partnerships, new collaborations, and future directions.

Dispute Resolution Process

- Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between the award recipient and CDC/NIOSH may be brought to Dispute Resolution. A Dispute Resolution Panel will be convened, composed of three members: a designee of the Steering Committee, chosen without CDC/NIOSH staff voting; a CDC/NIOSH designee; and a designee with expertise in the relevant area, who is chosen by the other two. In cases of individual disagreement, the first member may be chosen by the individual awardee.
- This special dispute resolution procedure does not alter the awardee'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.

5. Reporting

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

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

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. 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**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) 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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) 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 period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:
    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
    - Research Aims: list each research aim/project

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

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

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

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

- New Budget Period Proposal:

- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

Outputs, Outcomes, and Research to Practice (r2p): Grantees must provide a brief statement about any research outputs, outcomes, and/or r2p developments that occurred during this reporting period. Please note the following:

- Outputs are the immediate products or direct result of research activities. Examples include publications, reports, conference proceedings, presentations/posters, investigator career development, databases, tools, methods, guidelines, recommendations, education and training materials.
- Outcomes can be measured over time as either intermediate or end. Intermediate outcomes are specific changes that occur as a result of research activities. Examples of intermediate outcomes include public or private policy changes, conduct of training or workshops based on project outputs, citations in the literature, inventions and patents, and adoption of technologies or methods developed by the researcher.
- r2p is the transfer and translation of knowledge, interventions, and technologies into highly effective prevention practices and products that are adopted into the workplace.

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

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

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

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

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://commons.era.nih.gov/commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contact
Bridgette E. Garrett, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 770-488-5715
Email: BGarrett@cdc.gov

Peer Review Contact
Michael Goldcamp, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Telephone: 304-285-5951
Email: MGoldcamp@cdc.gov

Financial/Grants Management Contact
Tesa W. Bryant
Office of Grants Services
Office of Financial Resources
Centers for Disease Control and Prevention
Telephone: 404-498-1094
Email: xcf8@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

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

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