

Part I Overview Information

Department of Health and Human Services

Participating Organizations

Centers for Disease Control and Prevention (CDC), (<http://www.cdc.gov>)

Components of Participating Organizations

National Institute for Occupational Safety and Health (NIOSH),
(<http://www.cdc.gov/niosh/homepage.html>)

Title: Prevention of Airborne Infections in Occupational Settings

The CDC policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH.

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 Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and of Section 20 (a) of the Occupational Safety and Health Act of 1970 (29 USC 669 (a)), and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>

Announcement Type

New

Request For Applications (RFA) Number: RFA-OH-06-002

Catalog of Federal Domestic Assistance Number(s):

93.262 Occupational Safety and Health Program

Key Dates

Release Date: January 18, 2006

Letter of Intent Receipt Date: March 17, 2006

Application Receipt Date: April 18, 2006

Peer Review Date: May-June, 2006

Council Review Date: June 2006

Earliest Anticipated Start Date: July 2006

Additional Information To Be Available Date (URL Activation Date): NA

Expiration Date: April 19, 2006

Due Date for E.O. 12372

Executive Order 12372 does not apply to this program

Additional Overview Content

Executive Summary

The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), invites applications to conduct research in basic, applied, or population research that will advance prevention of airborne infectious diseases in occupational settings.

- NIOSH intends to commit approximately one million dollars per year for this program.
- NIOSH intends to fund three to six new awards in response to this RFA.
- This funding opportunity will use the research R01 mechanism.
- For-profit organizations, non-profit organizations, public or private institutions, units of state government, domestic or foreign institutions, units of state tribal government, units of local government and faith-based or community-based organizations are eligible to apply.
- Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institutions to develop an application for support. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities, are encouraged to apply for NIOSH programs.
- Only one application per applicant may be submitted under this announcement.
- Applications must be prepared using the PHS 398 research grant application instructions and forms. The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.
- Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

Table of Contents

Part I Overview Information

Part II Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Section II. Award Information

1. Mechanism(s) of Support
2. Funds Available

Section III. Eligibility Information

1. Eligible Applicants
 - A. Eligible Institutions
 - B. Eligible Individuals
2. Cost Sharing or Matching
3. Other - Special Eligibility Criteria

Section IV. Application and Submission Information

1. Address to Request Application Information
2. Content and Form of Application Submission
3. Submission Dates and Times
 - A. Receipt and Review and Anticipated Start Dates
 1. Letter of Intent
 - B. Sending an Application
 - C. Application Processing
4. Intergovernmental Review
5. Funding Restrictions
6. Other Submission Requirements

Section V. Application Review Information

1. Criteria
2. Review and Selection Process
 - A. Additional Review Criteria
 - B. Additional Review Considerations
 - C. Sharing Research Resources
3. Anticipated Announcement and Award Dates

Section VI. Award Administration Information

1. Award Notices
2. Administrative and National Policy Requirements
3. Reporting

Section VII. Agency Contact(s)

1. Scientific/Research Contact(s)
2. Peer Review Contact(s)
3. Financial/ Grants Management Contact(s)

4. General Questions Contact(s)

Section VIII. Other Information - Required Federal Citations

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The CDC and NIOSH are committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This RFA addresses "Healthy People 2010" priority area(s) of reducing airborne infections in occupational settings and promote a health work environment and is in alignment with NIOSH's performance goal (s) to reduce transmission of airborne infections in workers including early responders, health care workers, and other occupational groups. For more information, see www.health.gov/healthypeople and www.whitehouse.gov/omb/mgmt-gpra/.

Purpose

Transmission of airborne infections to early responders, health care workers, and other occupational groups such as postal workers has become an important public health concern. Past experience with small pox and more recently with anthrax and severe acute respiratory virus (SARS) has increased the need for further research to prepare for potential outbreaks. The National Institute for Occupational Safety and Health (NIOSH) invites applications in basic, applied, or population research that will advance prevention of airborne infectious diseases in occupational settings.

Background

Airborne infectious diseases have become prominent public health concerns. The anthrax attacks of 2001 had a major impact on the U.S.A. Seven contaminated letters killed 5, infected at least 17, and lead to huge expenditures to prevent further infection. It is estimated that 42 million dollars were spent decontaminating the Hart Senate Office Building and other Capitol Hill offices and that decontamination of the Brentwood Postal Facility will ultimately cost another 100 million dollars. At very great expense, the Postal Service irradiated contaminated mail and continues to monitor mail for contamination with infectious agents. Severe acute respiratory syndrome (SARS) and avian influenza have also caused morbidity, mortality and very significant economic damage to affected countries.

In many cases, the impact of recent airborne infectious disease outbreaks has been worsened by insufficient knowledge concerning best practices for prevention. Improvements are needed in many areas. In the case of natural human to human transmission of disease, more sensitive and specific approaches are needed for early identification and isolation of infectious cases. In the case of environmental exposures, as would occur in bioterrorism, rapid detection of exposure might allow early deployment of interventions such as prophylactic antimicrobial treatment. Better approaches to exposure quantification and understanding of exposure-infection relationships are needed to develop rational approaches for respiratory protection and decontamination. Determination of appropriate respirator protection factors and acceptable levels of residual environmental contamination after clean up to effectively prevent disease transmission requires better understanding of exposure-response relationships.

Research is needed in many disciplines to improve approaches to prevention of airborne infections in occupational settings. Industrial hygiene, infection control, public health, microbiology, medicine, nursing, engineering, aerosol science, and other disciplines all have important roles in improving environmental controls, administrative controls, personal protective equipment, early identification of infected cases or exposures, immunization programs, and other measures to prevent spread of airborne infectious diseases in the occupational setting.

Objectives

The objective of this RFA is to improve prevention of airborne infectious diseases in occupational settings. While a variety of research approaches are acceptable, studies related to reduction of exposure by environmental or administrative controls, detection and quantification of exposure, documentation of exposure-response relationships, use of respirators or other personal protective equipment, or decontamination are desired. Studies

with a high likelihood of affecting real-world prevention practices are especially desirable. Studies focusing on development of new vaccines, diagnostic tests optimized for clinical disease management, bioterrorism, or disease treatments are not appropriate for this RFA.

Some examples of research areas appropriate for this RFA include, but are not limited to the following:

- Development of improved strategies for early identification and isolation of infectious cases.
- Development of improved approaches to detect and quantify airborne infectious agents and settled infectious agents with potential for re-aerosolization.
- Studies establishing exposure-response relationships for induction of disease by airborne infectious agents.
- Characterization of infectious aerosols generated by infectious people, biological weapons systems, or other sources. Determination of infectious aerosol size distribution and impact of factors such as temperature, humidity and UV irradiation on aerodynamic properties, viability and infectivity of these aerosols. Elucidating factors that affect re-aerosolization of settled agents. Developing approaches to predicting the relative importance of airborne and contact disease transmission.
- Engineering controls such as optimization of ventilation and other building characteristics, and UV germicidal irradiation.
- Issues in use of respirators to prevent transmission of airborne infectious diseases such as fit testing methods and interpretation, respirator selection, and innovative approaches to enable longer use or re-use of respirators when they are in short supply.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the R01 award mechanism(s).

As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats. For additional guidance for proper formatting see

<http://grants.nih.gov/grants/funding/modular/modular.htm>. Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise, follow the instructions for non-modular research grant applications.

2. Funds Available

NIOSH intends to commit approximately one million dollars in FY 2006 to fund three to six new grants in response to this RFA. An applicant may request a project period of up to five (5) years and a budget for direct costs up to \$300,000 dollars per year. The anticipated start date for new awards is July, 2006.

All estimated funding amounts are subject to availability of funds.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the CIO (s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation; see [NOT-OD-05-004](#).

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State Government
- Units of Local Government
- Eligible agencies of the Federal government
- Foreign Institutions

- Domestic institutions
- Units of State Tribal government
- Units of Local Tribal Government
- Faith-based or community-based organizations

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

2. Cost Sharing or Matching

Cost sharing is not required.

The most current Grants Policy Statement can be found at:

<http://grants.nih.gov/grants/policy/gps/>

3. Other-Special Eligibility Criteria

Only one application per applicant can be submitted under this announcement.

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

CDC Telecommunications for the hearing impaired: TTY 770-488-2783.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a Dun & Bradstreet (D&B) Data Universal Numbering System number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

Foreign Organizations

Several special provisions apply to applications submitted by foreign organizations:

- Charge back of customs and import fees is not allowed.
- Format: every effort should be made to comply with the format specifications which are based upon a standard US paper size of 8.5" x 11."
- Funds for up to 8% administrative costs (excluding equipment) can now be requested (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-028.html>)
- Organizations must comply with federal/CDC policies on human subjects, animals, and biohazards.
- Organizations must comply with federal/CDC biosafety and biosecurity regulations. See Section VI. 2. Administrative Requirements [Section IV.3.A](#). Submission times are not applicable.

3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: March 17, 2006

Application Receipt Date(s): April 18, 2006

Peer Review Date: May-June, 2006

Council Review Date: June 2006

Earliest Anticipated Start Date: July 2006

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research.
- Name, address, and telephone number of the Principal Investigator.
- Names of other key personnel.
- Participating institutions.
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIOSH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV.3.A

The letter of intent should be sent to:

Charles N. Rafferty, Ph.D.
Assistant Director for Review and Policy
Office of Extramural Programs/NIOSH
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2582
FAX: (404) 498-2571
Email: COR9@cdc.gov

3.B. Sending an Application

Applications follow the PHS 398 application instructions for content and formatting of your applications. If the instructions in this announcement differ in any way from the PHS 398 instructions, follow the instructions in this announcement.

Applications must be prepared using the research grant applications found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Using the RFA Label: The RFA label available in the PHS 398 application instructions must

be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at:

<http://grants.nih.gov/grants/funding/phs398/labels.pdf>.

Personal deliveries to CSR of applications are no longer permitted (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>).

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Charles N. Rafferty, Ph.D.
Assistant Director for Review and Policy
Office of Extramural Programs/NIOSH
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2582
FAX: (404) 498-2571
Email: COR9@cdc.gov

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above (Section IV.3.A.). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by NIOSH and PGO. Incomplete and non-responsive applications will not be reviewed.

CDC will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

All CDC awards are subject to the terms and conditions, cost principles, and other considerations described in the PHS Grants Policy Statement at <http://grants.nih.gov/grants/policy/gps/index.html>.

Additional guidance can be found at [NIH Grants Policy Statement](#). The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds relating to the conduct of research will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

6. Other Submission Requirements

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Your research plan should address activities to be conducted over the entire project period.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

2. Review and Selection Process

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIOSH in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by NIOSH.

The goals of CDC-supported research are to advance the understanding of health promotion and prevention of disease, injury, and disability, and enhance preparedness. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does the application propose to investigate organisms and exposures of health concern in occupational environments?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the application propose improved strategies, methods or approaches to detect quantify, establish exposure–dose relationships, or controls to improve prevention of airborne infectious diseases in occupational settings?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. Additional CDC

Requirements under AR-1 Human Subjects Requirements can be found on

<http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed. Additional CDC Requirements under AR-3 Animal Subjects Requirements can be found on <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Resources

Not Applicable.

3. Anticipated Announcement and Award Dates

Not Applicable.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIOSH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIOSH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer (GMO) is the authorizing document. This document will be mailed and/or emailed to the recipient fiscal officer identified in the application.

Selection of the application for award is not an authorization to begin performance. Any cost incurred before receipt of the NoA is at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also [Section IV.5. Funding Restrictions](#).

2. Administrative and National Policy Requirements

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about policy requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Additional requirements can be found in Section VIII. Other Information of this document or on the CDC website at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. These will be

incorporated into the NoA by reference.

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement. NIOSH follows this policy.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Adele M. Childress, Ph.D.; M.S.P.H.
Office of Extramural Programs/NIOSH
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2509
FAX: (404) 498-2571
Email: AChildress@cdc.gov

2. Peer Review Contacts:

Charles N. Rafferty, Ph.D.
Assistant Director for Review and Policy
Office of Extramural Programs/NIOSH
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2582
FAX: (404) 498-2571
Email: COR9@cdc.gov

3. Financial or Grants Management Contacts:

Cynthia Mitchell
Acquisition and Assistance Field Branch
Centers for Disease Control and Prevention
626 Cochran Mill Road
Pittsburgh, PA 15236-0070
Telephone: (412) 386-6434
FAX: (412) 386- 6429
Email: cmitchell@cdc.gov

Section VIII. Other Information

Required Federal Citations

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). Additional CDC Requirements under AR-1 Human Subjects Requirements can be found on <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Use of Animals in Research:

Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable. Additional CDC Requirements under AR-3 Animal Subjects Requirements can be found on <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic

groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>). NIOSH supports this policy.

Sharing Research Data:

Investigators submitting an NIOSH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIOSH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIOSH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers

are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Smoke-Free Workplace Requirements

CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Healthy People 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of

policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

Accounting System Requirements

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

Capability Assessment

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

Proof of Non-profit Status

Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: (a) a reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of

tax-exempt organizations described in section 501(c)(3) of the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State Attorney General, or other appropriate State Official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status; (e) any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

Security Clearance Requirement

All individuals who will be performing work under a grant or cooperative agreement in a CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardee employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at CDC must undergo a security clearance process.

Research Integrity

The signature of the institution official on the face page of the application submitted under this Program Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."

The regulation places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity's (ORI) Assurance Program.

For examples:

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary (DHHS) that the applicant: (1) Has established an administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states that: "an applicant or recipient institution shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be

submitted to the [ORI], on a form prescribed by the Secretary,...and updated annually thereafter...(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

An additional policy is added in the year 2000 that "requires research institutions to provide training in the responsible conduct of research to all staff engaged in research or research training with PHS funds.

Compliance with Executive Order 13279

Faith-based organizations are eligible to receive federal financial assistance, and their applications are evaluated in the same manner and using the same criteria as those for non-faith-based organizations in accordance with Executive Order 13279, Equal Protection of the Laws for Faith-Based and Community Organizations. All applicants should, however, be aware of restrictions on the use of direct financial assistance from the Department of Health and Human Services (DHHS) for inherently religious activities. Under the provisions of Title 45, Parts 74, 87, 92 and 96, organizations that receive direct financial assistance from DHHS under any DHHS program may not engage in inherently religious activities, such as worship, religious instruction, or proselytization as a part of the programs or services funded with direct financial assistance from DHHS. If an organization engages in such activities, it must offer them separately, in time or location, from the programs or services funded with direct DHHS assistance, and participation must be voluntary for the beneficiaries of the programs or services funded with such assistance. A religious organization that participates in the DHHS funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from DHHS to support inherently religious activities such as those activities described above. A faith-based organization may, however, use space in its facilities to provide programs or services funded with financial assistance from DHHS without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from DHHS retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of DHHS funded activities. For further guidance on the use of DHHS direct financial assistance see Title 45, Code of Federal Regulations, Part 87, Equal Treatment for Faith-Based Organizations, and visit the internet site: <http://www.whitehouse.gov/government/fbci/>

Health Insurance Portability and Accountability Act Requirements

Recipients of this grant award should note that pursuant to the Standards for Privacy of

Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



Department of Health
and Human Services



National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892