

# Part I Overview Information

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## United States Department of Health and Human Services (HHS)

### Issuing Organization

Centers for Disease Control and Prevention at <http://www.cdc.gov/>

### Participating Organizations

Centers for Disease Control and Prevention at <http://www.cdc.gov/>

### Components of Participating Organizations

National Institute for Occupational Safety and Health at <http://www.cdc.gov/niosh>

## Title: Extension of the World Trade Center Registry (U50)

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

**Authority:** This program is authorized 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 951(a); Section 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. The Catalog of Federal Domestic Assistance number is 93.262.

**Announcement Type:** Renewal

### Instructions for Submission of Electronic Research Applications:

**NOTICE:** Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

This FOA must be read in conjunction with the application package instructions included with this announcement on [Grants.gov/Apply for Grants](http://Grants.gov/Apply for Grants) (hereafter referred to as, Grants.gov/Apply.)

A registration process is necessary before submission, and applicants are strongly encouraged to start the process at least four weeks prior to the grant submission date. See [Section IV](#).

### Two steps are required for on time submission:

1) The application must be successfully received by Grants.gov no later than 5:00 p.m. Eastern Standard Time on the application submission receipt date (see "[Key Dates](#)" below.)

2) Applicants must complete a verification step in the Electronic Research Administration (eRA [Commons](#)) within two business days of notification. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the eRA [Commons](#).

## **Funding Opportunity Announcement (FOA) Number: RFA-OH-09-002**

**Catalog of Federal Domestic Assistance Number(s):** 93.262

### **Key Dates**

[See Section IV.3.A.](#)

### **Due Date for E.O. 12372**

Executive Order 12372 does not apply to this program.

## **Executive Summary**

- Purpose. The purpose of this program is to extend and expand the World Trade Center Health Registry developed and managed by the New York City Department of Health and Mental Hygiene in a cooperative agreement with CDC. The new project will ensure on-going data collection for victims of the September 11, 2001, terrorist attacks on the World Trade Center. The registry will continue to provide a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster.
- Mechanism of Support. This program uses the U50 award mechanism.
- Funds Available and Anticipated Number of Awards. \$12M available. One anticipated award
- Budget and Project Period. Maximum of 3 year project period.
- Eligible Institutions/ Organizations. Institutions/organizations listed in [Section III.1.A](#) are eligible to apply.
- Eligible Project Directors/Principal Investigators (PDs/PIs). Any individual with the skills, knowledge, and resources necessary to carry out the proposed occupational safety and health program 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 NIOSH programs.
- Number of Applications. An applicant institution may submit only one application under this announcement.
- Resubmissions. Resubmission applications will not be accepted.
- Renewals. Applicants may not submit renewal applications.
- Application Materials. Application materials may be obtained from [www.grants.gov](http://www.grants.gov). Applicants must follow the instructions provided or the application will be returned as non-responsive.
- Hearing Impaired. HHS/CDC Telecommunications for the hearing impaired is available at the following number: TTY 770-488-2783.

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### Section I. Funding Opportunity Description

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#### 1. Research Objectives

The Centers for Disease Control and Prevention (CDC) announces the availability of funds for a cooperative agreement program with the New York City Department of Health and Mental Hygiene (NYCDOHMH) for the development of the World Trade Center (WTC) Registry. Measurable outcomes of the program will contribute to the following CDC strategic goal in alignment with an HHS strategic goal: Increase the number of communities that protect and promote health and safety and prevent illness and injury to improve the safety, quality, affordability and accessibility of health care.

The purpose of this program is to extend and expand the World Trade Center Health Registry developed and managed by the New York City Department of Health and Mental Hygiene in a cooperative agreement with CDC. The new project will ensure on-going data collection for victims of the September 11, 2001, terrorist attacks on the World Trade Center. The registry will continue to provide a central, unified database to assess short and long term health effects among persons exposed to the WTC disaster.

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

### Section II. Award Information

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#### 1. Mechanism(s) of Support

This funding opportunity will use the HHS/CDC U50 activity code, which is a cooperative agreement assistance instrument. Under the U50 assistance instrument, the Recipient Organization retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, and with HHS/CDC staff is substantially involved as a partner with the Recipient Organization, as described in Section VI.2.A., "Cooperative Agreement".

#### 2. Funds Available

NIOSH intends to commit over a three-year period approximately \$12,000,000 in total costs (direct and indirect) to fund 1 application. The applicant may request more than \$4,000,000 in any year, but the total funding over three years will be limited to \$12,000,000. The anticipated start date for the renewal award is April 30, 2009.

All estimated funding amounts are subject to availability of funds.

If an applicant requests a funding amount greater than the three-year limit, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

### Section III. Eligibility Information

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## 1. Eligible Applicants

### 1.A. Eligible Institutions

Assistance will be provided only to New York City Department of Health and Mental Hygiene (NYCDOHMH). No other applications are solicited.

By virtue of its previous and ongoing work, NYCDOHMH is uniquely situated to conduct the work under this cooperative agreement for the following reasons:

1. NYCDOHMH was a major responder immediately following the WTC disaster, providing emergency medical assistance, environmental monitoring, setting up syndromic surveillance for biological attack, providing personal protection to responders, and providing health alerts and advice to residents.
2. NYCDOHMH is the point of entry into the public health system for the residents of New York City.
3. Using a collaborative approach, NYCDOHMH has designed and implemented the protocol for the initial data collection for this effort, as well as the first three-year follow-up data collection. The investigators have detailed knowledge of the data collection instruments, the data collection techniques, the data cleaning and verification methods, and the data analysis procedures that form the foundation for producing outputs on the health status of this special population.
4. NYCDOHMH possesses a full understanding of the history, rationale, legal, and policy aspects related to the creation of WTC Registry.
5. NYCDOHMH has strong linkages to all levels of the community required for gaining support and credibility for the enrollment of identified registry populations.
6. NYCDOHMH is now partnering with the New York City Health and Hospital Corporation to refer people for health care based on their special knowledge of the types of health conditions caused by exposures to WTC hazards.

## 2. Cost Sharing or Matching

Cost sharing or matching is not required.

The most current HHS Grants Policy Statement is available at:

[http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc)

## 3. Other-Special Eligibility Criteria

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

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To download a SF424 (R&R) Application Package and SF424 (R&R) Application Instructions for completing the SF424 (R&R) forms for this FOA, link to [Grants.gov/Apply](http://Grants.gov/Apply) and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at the following:

- Grants.gov Get Registered, [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)

- eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

IMPORTANT: both the applicant organization, as well as, the PD/PI must register in eRA Commons for an application to be accepted electronically. The Credentials Log-In, referenced in [Section IV. 2.](#) Content and Form of Application Submission, is obtained through Step #3 in the required actions below.

PD/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

The following three steps are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov Get Registered, [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:  
[Grants.gov Customer Support](#)  
Contact Center Phone: 800-518-4726  
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time  
Email [support@grants.gov](mailto:support@grants.gov)

2) Organizational/Institutional Registration in the eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

- To find out if an organization is already eRA Commons-registered, see the "[List of Grantee Organizations Registered in eRA Commons.](#)"
- Direct questions regarding the eRA Commons registration to:  
eRA Commons Help Desk  
Phone: 301-402-7469 or 866-504-9552 (Toll Free)  
TTY: 301-451-5939  
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time  
Email [commons@od.nih.gov](mailto:commons@od.nih.gov)

3) Project Director/Principal Investigator (PD/PI) Registration in the eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide.](#)

- The individual designated as the PD/PI on the application must also be registered in the eRA Commons. It is not necessary for PDs/PIs to register with Grants.gov.
- The PD/PI must hold a PD/PI account in the eRA Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
- This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (AOR/SO) or their designee who is already registered in the eRA Commons.
- Both the PD/PI and AOR/SO need separate accounts in the eRA Commons since both hold different roles for authorization and to view the application process.

Note that if a PD/PI is also an HHS peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](https://www.grants.gov) and the eRA [Commons](https://www.eRA Commons). The HHS/CDC strongly encourages applicants to use the Grants.gov electronic applications process and have organizations and PD/PIs complete all necessary registrations.

## 1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](https://www.grants.gov/apply).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA); although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact PGO TIMS: Telephone 770-488-2700, Email: [PGOTIM@cdc.gov](mailto:PGOTIM@cdc.gov)

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

## 2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide ([MS Word](#) or [PDF](#)).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to HHS/CDC. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by HHS/CDC (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Tips and Tools for Navigating Electronic Submission" on the front page of "[Electronic Submission of Grant Applications](#)."

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/Apply](https://www.grants.gov/apply) will include all applicable components, mandatory and optional. A completed application in response to this FOA will include the following components:

### Required Components:

- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- Research & Related Budget

- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist

## Optional Components:

PHS398 Cover Letter File  
Research & Related Sub award Budget Attachment(s) Form

- o Note: While both budget components are included in the SF424 (R&R) forms package, the CDC U50 (activity code) uses ONLY the detailed Research & Related Budget. (Do not use the PHS 398 Modular Budget.)

## 3. Submission Dates and Times

See Section IV.3.A for details

### 3. A. Submission, Review and Anticipated Start Dates

Release/Posted Date: January 27, 2009  
Application Submission Receipt Date: March 12, 2009  
Peer Review Date: March 31, 2009  
Council Review Date: April, 2009  
Earliest Anticipated Start Date: April 30, 2009

#### 3.A.1. Letter of Intent

A letter of intent is not applicable to this funding opportunity announcement.

#### 3.B. Submitting an Application to NIH

Applications submitted to NIOSH are processed through NIH. To submit an application in response to this FOA, applicants should access this FOA via <http://www.grants.gov/Apply> and follow Steps 1-4. Note: Applications must only be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

#### 3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See [Section IV.3.A.](#) for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary. **IF YOU CAN'T VIEW IT, WE CAN'T REVIEW IT.**

If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the CDC, PGO, Technical Information Management Section, after two business days.

Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two day viewing window. This option should be used if the AOR/SO determines that warnings should be addressed. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors) it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.

If the two day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. HHS/CDC will not penalize the applicant for an eRA Commons or Grants.gov system issue.

If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted but it will be subject to the CDC late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment and must refer only to Commons errors and/or technical errors.

Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two days.

Upon receipt, applications will be evaluated for completeness and responsiveness by NIOSH and HHS/CDC Procurement and Grants Office (PGO). HHS/CDC will not review incomplete and non-responsive applications.

There will be an acknowledgement of receipt of applications from Grants.gov and the eRA [Commons](#).

**Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on their application status in the Commons.**

## 4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

## 5. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement: [http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc)

Restrictions, which applicants must take into account while writing their budgets, are as follows:

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

## 6. Other Submission Requirements

Awardees upon acceptance of Notice of Award (NoA), must agree to the "Cooperative Agreement Terms and Conditions of Award" in [Section VI. "Award Administration Information"](#).

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. If submitting electronically, use a PDF version of the agreement, attach it in Grants.gov under “Other Attachments”, and title it appropriately.

Applicants’ research plan(s) should address activities they will conduct over the entire project period. Each of the responsibilities in [Section VI. 2.A.1](#) should be described in the proposed project plans.

The HHS/CDC requires the PD/PI to fill in his/her eRA Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component. The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided

at CCR registration with Grants.gov. For additional information, see Registration FAQs – Important Tips -- [Electronic Submission of Grant Applications](#).

## Research Plan Component Sections

While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to HHS/CDC in PDF format, filenames must be included with no spaces or special characters, and a PDF extension must be used. Do not include any information in a header or footer of the attachments. A header will be system-generated that references the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered; therefore, do not number the pages of your attachments. Your research plan must not exceed 50 pages. If your research plan exceeds the page limitation, your application may be considered unresponsive and ineligible for review.

The following materials may be included in the Appendix:

Up to ten publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Note that not all grant activity codes allow the inclusion of publications.

- Publications in press: Include only a publication list with a link to the publicly available online journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.
- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Graphic images of gels, micrographs, etc. provided that the image (may be reduced in size) is also included within the (stated) page limit of Items 2-5 of the Research Plan component. No images may be included in the Appendix that are not also represented within the Research Plan.

Please note the following restriction on appendix attachments: The Research Plan [Appendix attachments](#) are limited to 10 attachments. Appendices are uploaded as attachments in the PHS 398 Research Plan form, in field #18, within the electronic application package. An applicant will receive an error message if the number of appendix attachments exceeds 10, which will result in an unsuccessful submission of the application. You may include more than one publication, or other allowable appendix material, within one attachment; however, do not let your attachments exceed 10."

Do not to use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the relevant policies and procedures may not be considered in the review process. Applicants are reminded to review specific FOAs for any additional program-specific guidance on Appendix material and other application requirements.

## Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation they will provide, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not the awardee will place any conditions on their use), and the mode of data

sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The HHS/CDC data sharing policy is available at <http://www.cdc.gov/od/pgo/funding/ARs.htm> under Additional Requirements 25 Release and Sharing of Data. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

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

## Sharing Research Resources

HHS policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (see the HHS Grants Policy Statement [http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc).) Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by the HHS/CDC Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

## Section V. Application Review Information

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### 1. Criteria

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

### 2. Review and Selection Process

If the application is complete and responsive to the FOA, it 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. Each of the responsibilities in [Section VI. 2.A.1](#) should be described in the proposed project plans.

- Proposed Program (50 percent)

The extent to which the applicant's proposal and protocol addresses (a) the approach, feasibility, adequacy, and rationale of the proposed project design; (b) the technical merit of the proposed project, including the degree to which the project can be expected to yield results that meet the program objective as stated in Part II, [Section I](#), 1. Research Objectives of this announcement and the technical merit of the methods and procedures (including quality assurance and quality control procedures) for the proposed project; (c) the proposed project timeline, including clearly established project objectives for which progress toward attainment can and will be measured objectively by defined methods; (d) the proposed community outreach strategy; and (e) the proposed method to disseminate the results to State and local public health officials, community residents, and other concerned individuals and organizations.

- Program Personnel (30 percent)

The extent to which the proposal has described (a) the qualifications, experience, and commitment of the principal investigator (or project director) and his/her ability to devote adequate time and effort to provide effective leadership; and (b) the competence of associates to accomplish the proposed activities, their commitment, and the time they will devote.

- Applicant Capability and Coordination Efforts (20 Percent)

The extent to which the proposal has described (a) the capability of the applicant's administrative structure to foster successful scientific and administrative management of a study; and (b) the capability of the applicant to demonstrate an appropriate plan for interaction with the community.

As part of the initial merit review, the application will receive a written critique.

A second level of review for programmatic value will be conducted by HHS/CDC/NIOSH.

## 2.A. Additional Review Criteria

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

**Protection of Human Subjects from Research Risk:** When human subjects are involved, HHS/CDC will assess the available protections from research risk that relate to their participation in the proposed research. [see the Research Plan, Section 2, item 8 on Human Subjects in the SF424 (R&R)] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. This review element is not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

**Inclusion of Women and Minorities in Research:**

Does the application adequately address the HHS/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 (see Section 2, item 9 Inclusion of Women and Minorities of the Research Plan component of the SF424 (R&R)).

**Care and Use of Vertebrate Animals in Research:** If applicants plan to use vertebrate animals in the project, HHS/CDC will assess the five items described under Section 2, item 12 Vertebrate Animals of the Research Plan component of the SF424 (R&R). Additional HHS/CDC Requirements under AR-3 Animal Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

**Biohazards:** If applicants propose the applicant has proposed materials or procedures that are potentially hazardous to research personnel and/or the environment, HHS/CDC will determine if the proposed protection is adequate.

## 2.B. Additional Review Considerations

**Budget and Period of Support:** The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. Is the number of person months listed for the effort of the PD/PI appropriate for the work proposed? Is each budget category realistic and justified in terms of the aims and methods? The

evaluation of the budget should not effect the priority score.

## 2.C. Sharing Research Data

Data Sharing Plan: HHS/CDC will assess the reasonableness of the data sharing plan. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The presence of a data sharing plan will be part of the terms and conditions of the award. The funding organization will be responsible for monitoring the data sharing policy.

## 2.D. Sharing Research Resources

HHS policy requires that recipients of grant awards make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. Please see <http://grants.nih.gov/grants/policy/gps/8postnew.htm#phs>. Investigators responding to this funding opportunity should include a plan on sharing research resources.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (HHS/PHS 2590 <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

# Section VI. Award Administration Information

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## 1. Award Notices

After the peer review of the application is completed, the applicant organization will receive a written critique called a "Summary Statement." The applicant organization and the PD/PI will be able to access the Summary Statement via the eRA Commons.

HHS/CDC will contact those applicants under consideration for funding for additional information.

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. HHS/CDC will mail and/or e-mail this document 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 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 are available [Section VIII. Other Information](#) of this document or on the HHS/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.

The following terms and conditions will be incorporated into the NoA and will be provided to the appropriate institutional official and a courteous copy to the PD/PI at the time of award.

## 2.A. Cooperative Agreement

The following terms of award are in addition to, and not in lieu of, otherwise applicable Office of Management and Budget (OMB) administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS/CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U50 an "assistance" instrument (rather than an "acquisition" instrument), in which substantial HHS/CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the HHS/CDC may share specific tasks and activities, as defined above.

### 2.A.1. Recipient Rights and Responsibilities

The Recipient will have the primary responsibility for the following:

- a. Outreach - Plan and implement strategies and approaches that will sustain general interest and knowledge about the WTC Registry to enhance continued participation. Utilize existing contacts with business and community groups and organizations to facilitate outreach.
- b. Public Information Responsiveness – Support and maintain a system for receiving and answering calls from the public regarding concerns, and questions on the WTC Registry (NYCDOHMH call center). Create and maintain a web site for the provision of easily accessible and up-to-date information about the WTC Registry.
- c. Database and Analysis Infrastructure - Certify that data are prepared for analysis within defined, optimal time frames. Develop mechanisms for sharing selected and appropriate data elements with other WTC-related organizations that are also serving people who are impacted by their exposure to hazards associated with the WTC experience. Verify protocols for protecting the database from security violations and confidentiality breaches. Verify protocols for database backup and recovery.
- d. Update information on WTC registrants – Establish infrastructure for regularly contacting WTC Registrants. Send letters requesting updated contact information to a large proportion of registrants, selected based on exposure category. Manage staff and data system for inputting and correcting registrant contact information.
- e. Data dissemination – Prepare regular reports on enumeration of registrant populations, descriptive summaries, and emerging patterns of exposure or health status.
- f. Registry Follow-Up Survey – Conduct a third round of the survey in order to create the basis for continuing the prospective analysis of the long-term health effects of the exposures associated with the WTC attacks and the aftermath.
- g. Health Status Surveys –Match registrants with cancer registries, hospitalization data, and vital records. Perform appropriate analysis and disseminate findings.
- h. External registry studies - Establish methods and process for permitting other researchers to use the registry. Set up system for other bona fide researchers to obtain under a formal request de-identified registry data. Set up and manage process for contacting consented registrants about other studies in which they may enroll.
- i. Program Evaluation - Conduct an assessment of (1) the relevance of the program's activities to improving the health status of the cohort and (2) the impact that the program has had in reducing illness. Measures of contribution should include outputs of the program and outcomes (intermediate or final) that are attributable to the program's activities. Quantitative measures should be included and explained.
- j. Consultation and Collaboration - Develop science based capacity for conducting epidemiological and demographic research related to the Registry under separate funding.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS/CDC policies.

### **2.A.2. HHS/CDC Responsibilities**

The HHS/CDC Scientific Program Officer and other scientists, as needed, will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below in collaboration with the recipient:

- a. Development and maintenance of the infrastructure for managing and conducting outreach activities.
- b. Development of information to be given to the public regarding concerns and questions on the WTC Registry, as well as communication materials that will inform and encourage enrollees to continue their participation.
- c. Evaluation of registry information and data that describe the status of the cohort on a regular basis.
- d. Consultation on the third round of the survey in achieving the objective of continuing to have the ability to evaluate prospectively the long-term health effects in this cohort associated with the WTC attacks.
- e. Consultation on health status surveys for selected samples of registrants.
- f. Consultation on the evaluation plans for the Registry to determine its relevance to the improvement of health for the cohort and measures of impact.
- g. Development of a system that will permit other researchers to use the registry data.

The HHS/CDC Scientific Program Officer will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the NoA.

### **2.A.3. Collaborative Responsibilities**

If the applicant proposes a steering committee to serve as a governing board for the award, the members will include the Principal Investigator, the HHS/CDC Scientific Program Officer, and experts from outside of the grantee institution as defined by the applicant.

## **3. Reporting**

Recipient Organization must provide HHS/CDC with an original, plus two hard copies of the following reports:

1. Non-Competing Grant Progress Report, (use form PHS 2590, posted on the HHS/CDC website, <http://www.cdc.gov/od/pgo/funding/forms.htm> and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, no less than 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application. The report must include a statement of the objectives, specific accomplishments for each objective, any problems related to achieving the objectives in accordance to the proposed timeframes in the application, solutions to problems encountered, outputs (e.g., publications, data sets, summary reports, descriptive statistics, etc.), and specific plans for the next budget period.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial, final performance reports, and [Final Invention Statement and Certification Form](#), no more than 90 days after the end of the project period.

Recipient Organization must forward these reports by the U.S. Postal Service or express delivery to the Grants Management Specialist listed in the "Agency Contacts" section of this FOA.

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.

## Section VII. Agency Contacts

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HHS/CDC encourages your inquiries concerning this FOA and welcomes the opportunity to answer questions from potential applicants. Inquiries can fall into three areas: scientific/research, peer review, and financial or grants management issues:

### 1. Scientific/Research Contacts:

Roy M. Fleming, Sc.D.  
Scientific Program Officer  
Department of Health and Human Services  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health  
1600 Clifton Road, Mailstop E-75  
Atlanta, Georgia, 30333  
Telephone: 404-498-2537  
E-mail: [RFleming@cdc.gov](mailto:RFleming@cdc.gov)

### 2. Peer Review Contacts:

George Bockosh  
Scientific Review Officer  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E., Mailstop E74  
Atlanta, GA 30333  
Telephone: (412) 386-6465  
FAX: (412) 386-6716  
Email: [GBockosh@cdc.gov](mailto:GBockosh@cdc.gov)

### 3. Financial or Grants Management Contacts:

Peter Grandillo, Jr.  
Grants Management Specialist  
Acquisition and Assistance Field Branch  
Centers for Disease Control and Prevention  
626 Cochran Mill Road  
Pittsburgh, PA 15236-0070  
Telephone: (412) 386-6834  
FAX: (412) 386- 6429  
Email: [PGrandillo@cdc.gov](mailto:PGrandillo@cdc.gov)

### 4. General Questions Contacts:

Technical Information Management Section  
CDC Procurement and Grants Office  
U.S. Department of Health and Human Services

2920 Brandywine Road  
Atlanta, GA 30341  
Telephone: 770-488-2700  
Email: PGOTIM@cdc.gov

## Section VIII. Other Information

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### Required Federal Citations

#### Human Subjects Protection

Federal regulations (45 CFR Part 46) 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 HHS/CDC Requirements under AR-1 Human Subjects Requirements can be found on the Internet at the following address: <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 PERSONS UNDER THE AGE OF 21 IN RESEARCH

The policy of CDC is that persons under the age of 21 must be included in all human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons not to include them. This policy applies to all CDC-conducted or CDC-supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) and 401(b) of 45 C.F.R. Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including persons under the age of 21. If persons under the age of 21 will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In an extramural research plan, the investigator should create a section titled "Participation of persons under the age of 21." This section should provide either a description of the plans to include persons under the age of 21 and a rationale for selecting or excluding a specific age range, or an explanation of the reason(s) for excluding persons under the age of 21 as participants in the research. When persons under the age of 21 are included, the plan must also include a description of the expertise of the investigative team for dealing with individuals at the ages included, the appropriateness of the available facilities to accommodate the included age groups, and the inclusion of a sufficient number of persons under the age of 21 to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at CDC will assess each application as being acceptable or unacceptable in regard to the age-appropriate inclusion or exclusion of persons under the age of 21 in the research project, in addition to evaluating the plans for conducting the research in accordance with these provisions.

The inclusion of children (as defined by the applicable law of the jurisdiction in which the research will be conducted) as subjects in research must be in compliance with all applicable subparts of 45 C.F.R. Part 46, as well as with other pertinent federal laws and regulations.

The policy of inclusion of persons under the age of 21 in CDC-conducted or CDC-supported research activities in foreign countries (including collaborative activities) is the same as that for research conducted in the United States.

### **Executive Order 12372 Review**

Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (E.O.) 12372. The order sets up a system for State and local governmental review of proposed Federal assistance applications. Applicants should contact their State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications and to receive instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each State affected.

Click on the following link to get the current SPOC list

<http://www.whitehouse.gov/omb/grants/spoc.html>

HHS/CDC does not guarantee to accept or justify its non-acceptance of recommendations that are received more than 60 days after the application deadline.

### **Public Health System Reporting Requirements**

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

- A. A copy of the face page of the application (SF 424).
- B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
  - 1. A description of the population to be served.
  - 2. A summary of the services to be provided.
  - 3. A description of the coordination plans with the appropriate state and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

### **Paperwork Reduction Act Requirements**

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant or a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

### **Smoke-Free Workplace Requirements**

HHS/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 FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at [www.healthypeople.gov](http://www.healthypeople.gov)

## **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 HHS/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, HHS/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 HHS/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 HHS/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 HHS/CDC funds should give close attention to isolating and separating the appropriate use of HHS/CDC funds from non-CDC funds. HHS/CDC also cautions recipients of HHS/CDC funds to be careful not to give the appearance that HHS/CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

## **Prohibition on Use of HHS/CDC Funds for Certain Gun Control Activities**

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control."

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This

prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, HHS/CDC interprets the language in the HHS/CDC's Appropriations Act to mean that HHS/CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

### **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 HHS/CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardees employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at HHS/CDC must undergo a security clearance process.

### **Peer and Technical Reviews of Final Reports of Health Studies – HHS/ATSDR**

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by Superfund Amendments and Reauthorization Act of 1986 (SARA), Section 104 (I)(13), and [42 U.S.C. 9604 (I)] requires all studies and results of research (other than public health assessments) that ATSDR carries out or funds in whole or in part will be peer reviewed by ATSDR. The ATSDR peer review process for final reports requires that:

1. Studies must be reported or adopted only after appropriate peer review.
2. Studies shall be peer reviewed within a period of 60 days to the maximum extent practical.
3. Studies shall be reviewed by no fewer than three or more than seven reviewers who:
  - a. Are selected by the Assistant Administrator, ATSDR;

- b. Are disinterested scientific experts;
- c. Have a reputation for scientific objectivity; and
- d. Who lack institutional ties with any person involved in the conduct of the study or research under review.

HHS/ATSDR encourages rapid reporting and interpretation of laboratory results and reference ranges back to individual participants. However, if summary tables or distribution of laboratory results are prepared using the study data, this is considered a preliminary finding and will require ATSDR technical and peer review prior to release.

When, in the opinion of the investigator(s), a public health concern exists requiring the release of summary study statistics prior to the completion of the study, the investigator must obtain concurrence from HHS/ATSDR prior to releasing the summary statistics. A request for HHS/ATSDR concurrence for the release of information must be documented in a letter to HHS/ATSDR and should outline the public health concern, the investigator's interpretation of the concern and recommended response, and the draft document proposed for release by the investigator. HHS/ATSDR will provide a technical review and peer review within ten working days to the maximum extent possible. At sites where HHS/ATSDR must coordinate with another Federal agency, this requires additional time. Summary statistics may be released only after peer review. The release of summary statistics does not preclude the requirement for a final report.

By statute, the reporting of preliminary studies and preliminary research results to the public is not acceptable without prior review by HHS/ATSDR. This includes manuscripts prepared for publication, presentations at scientific meetings and reporting of preliminary findings to the community or the media.

#### Final Report

1. The final report for every study should include a detailed description of the problem, hypothesis, methods, results, conclusions, and recommendations that constitute a complete performance record of the study. A copy of the suggested format for the final report will be supplied by HHS/ATSDR to the investigator.

2. HHS/ATSDR is responsible for the technical and peer review of the draft final reports of any study that it funds prior to the submission of the final report. This will allow the recipient to incorporate technical and peer review comments into the final report. Responses to all HHS/ATSDR required technical and peer review comments should be summarized in a letter to HHS/ATSDR. This letter should also include the investigator's response to each comment and a rationale for those responses. Based upon the comments of the technical and peer reviewers, modifications in the study report may result. The modified study report should accompany the letter to HHS/ATSDR.

3. Following the steps outlined above, a final report of all studies and results of research carried out or supported by HHS/ATSDR must be submitted to the Procurement and Grants Office with a copy furnished to HHS/ATSDR.

All requirements, including peer review, technical review, and cost recovery, are applicable to award recipients and any subcontractors employed by the award recipient. Failure to comply with these requirements could adversely affect future funding.

#### **Cost Recovery – HHS/ATSDR**

CERCLA, as amended by SARA, provides for the recovery of costs incurred for response actions at each Superfund site from potentially responsible parties. The recipient would agree to maintain an accounting system that will keep an accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated cost including indirect cost, as appropriate for the site. The recipient would also maintain documentation that describes the site-specific response actions taken with respect to the site, e.g., contracts, work assignments,

progress reports, and other documents that describe the work performed at a site. The recipient will provide the site-specific costs and description of response actions taken with the supporting documentation upon request by HHS/ATSDR. The recipient will retain the documents and records to support these financial transactions and documentation of work performed, for possible use in a cost recovery case, for a minimum of ten years after submission of a final financial status report, unless there is litigation, claim, negotiation, audit or other action involving the specific site, then the records will be maintained until resolution of all issues on the specific site.

### **Third Party Agreements – HHS/ATSDR**

Applicant must justify the need to use a contractor. If contractors are proposed, the following must be provided: (1) name of contractor, (2) method of selection, (3) period of performance, (4) detailed budget, (5) justification for use of contractor, and (6) assurance of non-conflict of interest.

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the recipient and the third party.

The written agreement shall, at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the terms of the grant and/or cooperative agreement, including requirements concerning technical review (ATSDR selected reviewers), ownership of data, and the arrangement for copyright when publications, data, or other copyrightable works are developed under or in the course of work under a PHS grant-supported project or activity.
2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal government purposes.
3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the government's right in that work.
4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.
5. State non-conflict of interest concerning activities conducted for HHS/ATSDR and site-remediation activities for other parties.

The written agreement required shall not relieve the recipient of any part of its responsibility or accountability to PHS under the cooperative agreement. The agreement shall, therefore, retain sufficient rights and control to the recipient to enable it to fulfill this responsibility and accountability.

### **Small, Minority, And Women-owned Business**

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.

2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

## **Research Integrity**

The signature of the institution official on the face page of the application submitted under this Funding Opportunity Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 93, Subparts A-E, entitled PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT.

The regulation places requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity (ORI) (<http://ori.hhs.gov./policies/statutes.shtml>).

For example:

Section 93.301 Institutional assurances. (a) General policy. An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize [[Page 28389]] funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI. (b) Institutional Assurance. The responsible institutional official must assure on behalf of the institution that the institution-- (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.

## **Compliance with Executive Order 13279**

Faith-based organization 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. HHS/CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and HHS/CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

## **Release and Sharing of Data**

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the HHS/CDC data sharing agreement will be released as follows:

- a. In a timely manner.
- b. Completely, and as accurately as possible.
- c. To facilitate the broader community.
- d. Developed in accordance with CDC policy on Releasing and Sharing Data.

April 16, 2003, <http://www.cdc.gov/od/foia/policies/sharing.htm>, and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, <http://www.whitehouse.gov/omb/circulars/a110/a110.html> and Freedom of Information Act (FOIA) <http://www.state.gov/m/a/ips/>.

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide HHS/CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. HHS/CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

## **National Historic Preservation Act of 1966**

### **(Public Law 89-665, 80 Stat. 915)**

The grantee's signature on the grant application attests to their: (1) knowledge of the National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915); and (2) intent to ensure all grant related activities are in compliance with referenced public law, as stated:

- a. Section 106 of the National Historic Preservation Act (NHPA) states:

*The head of any Federal agency, having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any State and the head of any Federal department or independent state agency having authority to license any undertaking, shall, prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or is eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this ACT a reasonable opportunity to comment with regard to such undertaking.*

- b. Additionally, the NHPA also contains the following excerpt that forbids "anticipatory demolition:"

*Each Federal agency shall ensure that the agency will not grant a loan, loan guarantee, permit, license, or other assistance to an applicant who, with intent to avoid the requirements of Section 106 of this Act, has intentionally, significantly, adversely affected a historic property to which the grant would relate or, having legal power to prevent it, allowed such significant adverse effect to occur, unless the agency, after consultation with the Council, determines that circumstances justify granting such assistance despite the adverse effect created or permitted by the applicant.*

## **Conference Disclaimer and Use of Logos**

{Mandatory for all grants and cooperative agreements.}

**Disclaimer:** Where a conference is funded by a grant or cooperative agreement, a sub grant or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

*“Funding for this conference was made possible [in part] by [insert grant or cooperative agreement award number] from the Centers for Disease Control and Prevention(CDC) or the Agency for Toxic Substances and Disease Registry (ATSDR) . The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”*

**Logos:** Neither the HHS nor the CDC (“CDC” includes ATSDR) logo may be displayed if such display would cause confusion as to the source of the conference or give the false appearance of Government endorsement. A non-federal entity’s unauthorized use of the HHS name or logo is governed by U.S.C. § 1320b-10, which prohibits the misuse of the HHS name and emblem in written communication. The appropriate use of the HHS logo is subject to the review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials under a grant, cooperative agreement, contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for the use of the logo in sufficient detail to assure a complete depiction and disclosure of all uses of the Government logos, and to assure that in all cases of the use of Government logos, the written consent of either the Project Officer or the Grants Management Officer has been received.