

(CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised list of the 275 most hazardous substances was announced in the **Federal Register** on October 21, 1999 (64 FR 56792). For prior versions of the list of substances see **Federal Register** notices dated November 17, 1997 (62 FR

61332); April 29, 1996 (61 FR 18744); April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); and February 28, 1994 (59 FR 9486).

Notices (63 FR 56191) and (62 FR 55818) announcing the availability of the draft toxicological profiles for public review and comment were published in the **Federal Register** on October 21, 1998 or October 28, 1997 with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notices bear the docket control numbers ATSDR-137 or

ATSDR-127. This material is available for public inspection at the Division of Toxicology, Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia, (not a mailing address) between 8:00 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of one new final and six updated final toxicological profiles comprising the twelfth set prepared by ATSDR. The following toxicological profiles are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1-800-553-6847. There is a charge for these profiles as determined by NTIS.

Toxicological profile	NTIS order No.	CAS No.
Twelfth Set:		
1. Arsenic	PB2000-108021	007440-38-2
2. Chromium	PB2000-108022	007440-47-3
3. Endosulfan	PB2000-108023	000115-29-7
Endosulfan, alpha	000959-98-8
Endosulfan, sulfate	001031-07-8
Endosulfan, beta	33213-65-9
4. Ethion	PB2000-108024	00563-12-2
5. Manganese	PB2000-108025	007439-96-5
Manganese chloride	007773-01-5
Manganese dioxide	001313-13-9
Maneb	012427-38-2
Methylcyclopentadienyl Manganese Tricarbonyl	012108-13-3
6. Methylene Chloride	PB2000-108026	000075-09-2
7. Toluene	PB2000-108028	000108-88-3

Dated: November 9, 2000.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01011]

Improving Contact Investigations in Foreign-Born Populations; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year 2001 funds for a cooperative agreement for improving contact investigations in foreign-born populations. This program addresses the "Healthy People 2010," focus areas of Immunization and Infectious Diseases.

For the conference copy of "Healthy People 2010," visit the internet site <http://www.health.gov/healthypeople>.

The purpose of this cooperative agreement is to (1) improve contact identification for foreign-born (FB) TB cases; (2) improve completeness and timeliness of screening for identified contacts to FB TB cases; (3) improve the interpretation of screening results for contacts to FB TB cases in [a] the context of screening results for U.S.-born contacts to the same cases and [b] using serum immunologic profile (IFN-gamma and TNF-alpha) and results of skin test screening with non-tuberculous mycobacterial antigens to aid interpretation of screening results for FB contacts; and (4) improve completion of treatment for latent TB

infection for foreign-born contacts to pulmonary TB cases. These funds will be used to provide information for public health officials and policy makers to better understand methods for conducting contact investigations in FB populations and will provide improved completeness and timeliness of screening, interpretation of screening results, and treatment for latent TB infection for FB contacts to pulmonary TB cases.

This cooperative agreement will provide funds to build capacity at state and local health departments to conduct and implement protocol-driven epidemiologic and operational research. Such actions are consistent with recommendations issued by the Advisory Council for the Elimination of Tuberculosis (ACET) calling for decisive actions to: (1) Better understand the changing epidemiology of TB to rebuild the public health infrastructure; (2) identify challenges and opportunities for TB control in an era of changes in health care organizations and delivery; (3) recognize the interdependence of global TB and TB in the United States; and (4) develop and evaluate new tools for TB diagnosis, treatment and prevention.

B. Eligible Applicants

Assistance will be provided only to official public health agencies of States and territories, or their bona-fide agents that are (1) current recipients of the Tuberculosis Cooperative Awards announced in PA 00001 and (2) reported 200 or more TB cases in 1999, of which at least 100 must be among foreign-born persons. Eligible applicants are the states of Arizona, California, Florida, Georgia, Illinois, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Pennsylvania, Texas, Virginia, and Washington and the cities of Chicago, New York, Houston, Los Angeles, and San Francisco.

C. Availability of Funds

Approximately \$625,000 is available in FY 2001 to fund up to 4 awards for the initial 12-month budget period within a project period of 2 years. It is expected that the average award would be \$200,000 per year, ranging from \$175,000 to \$235,000. Funding estimates may change.

It is anticipated that awards will begin on or about February 15, 2001. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Direct Assistance

Applicants may request Federal personnel as direct assistance in lieu of a portion of financial assistance.

Use of Funds

Categorical funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds for contractual services may be requested; however, the grantee, as the direct and primary recipient of grant funds, must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party or provide funds to an ineligible party. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant state or local health department funds or for inpatient care or construction of facilities. Funds may not be used to purchase drugs for treatment. In addition, recipients must maintain clear accounting records to demonstrate that the funding awarded under this cooperative agreement is used toward the activities under this announcement and remains separate from any funding the recipient may be awarded under other mechanisms.

Funding Preference

Funding preference will be applied to ensure a balance of sites with exclusively urban populations, exclusively rural populations, and both urban and rural populations.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under 1. (Recipient Activities), and CDC will be responsible for conducting activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Access patients with tuberculosis, latent tuberculosis infection, or recent exposure to persons with active tuberculosis ("contacts") in the implementation of protocols for epidemiologic and operational research.

b. Conduct site-specific epidemiologic and operational research activities in TB which rely upon the implementation of common, agreed-upon study protocols.

c. Within 3 months of award, attend an investigator meeting at CDC with the CDC Project Officer to develop a study protocol, questionnaires, and data abstraction forms.

d. Promptly obtain all necessary human subjects protections assurances from the Office for Human Research

Protections (OHRP). Submit protocol to local IRB and work with CDC to finalize protocol with appropriate approvals from the local IRB and CDC IRB. Ensure that the study is conducted according to the IRB-approved protocol, including that all policies to provide data security and protect confidentiality are implemented.

e. Complete retrospective review of contact investigations done in the 12 months before this project according to protocol. This will include reviews of existing health department records of TB cases, their contacts, and the contact investigations.

f. Complete survey of recent TB cases, their contacts, and community leaders to identify social networks and major contact sites, and to refine questions for the structured interview format to be used in case and contact interviews in the prospective phase of the study.

g. Attend an investigator meeting at CDC with the CDC Project Officer to develop a prospective study protocol. Input from an ethnographer, results of the retrospective foreign-born study, results of the social networking survey, and preliminary results from the prospective US-born contact investigation study already ongoing at CDC will be considered in developing this protocol.

h. Conduct prospective study of all foreign-born culture-positive pulmonary TB cases age >15 years of age reported during a specified 12-month period and all their contacts. TB cases within each project area will be selected according to the protocol and their medical records will be reviewed. Cases will be interviewed in a structured format according to the study protocol. It is anticipated that there may be multiple interviews of the source case to obtain detailed information. Patients whose HIV status is not known will be encouraged to undergo HIV testing as per CDC recommendations. An example of the anticipated protocol activities is summarized in Attachment 1.

i. Interview contacts. Review medical records of contacts using a standard data abstraction form. It is anticipated that multiple interviews with contacts may be needed to obtain detailed information. Contacts whose HIV status is unknown will be offered HIV testing. All contacts without evidence of prior *Mycobacterium tuberculosis* infection or disease will receive a tuberculin skin test when first identified as a contact and at 12 weeks after their last contact with the case while the case was infectious. Those with positive tuberculin skin tests will be evaluated for preventive or curative therapy as indicated.

j. Test contacts with a panel of non-tuberculous mycobacterial antigens to determine whether supplementing tuberculin skin test screening with these antigens results in improved identification of persons recently infected with *M. tuberculosis*.

k. Obtain serum from close contacts and test for a number of cytokines known to be associated with the immune response to *M. tuberculosis* infection. This information will be used to determine whether cytokine profiles are a useful supplement to tuberculin skin test screening for determining whether recent *M. tuberculosis* transmission has occurred.

l. Conduct targeted tuberculin skin test screening in locations where the TB case spent time according to procedures and criteria specified in the study protocol.

m. Monitor contacts with latent TB infection to determine rates of treatment for latent TB infection recommendation, initiation, and completion. Reason for not recommending, initiating, or completing therapy will be delineated.

n. If secondary cases are identified, send *M. tuberculosis* isolates from the cases and their source case to the designated regional laboratory for DNA fingerprints.

o. Ensure that all data collected are maintained in confidential and secured files.

p. Send questionnaires and data abstraction forms for study participants to the CDC in accordance with the frequency specified in the protocol.

2. CDC Activities

a. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. Assist in development of a study protocol for retrospective, social networking survey, and prospective portions of the study.

b. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Organize and host a meeting at CDC with all the principal investigators within 3 months of awards being granted.

d. Assist in development of questionnaires and data abstraction forms for collecting and reporting results.

e. Collaborate as necessary in training the persons interviewing cases and contacts and doing the data abstraction from medical records.

f. Assist as needed and review the results of data analysis done locally.

g. Prepare study report and disseminate findings.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 15 double-spaced on 8½ by 11" pages (excluding budget justification), printed on one side, with one inch margins, and un-reduced font. Applications must be developed in accordance with CDC Form 0.1246(E). Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and each copy of the application must be submitted unstapled and unbound. Materials which should be part of the basic plan should not be in the appendices. For the budget section, submit a Form 424A (included in the Application Package) and detailed line-item justification for this focus area project. Applicants should follow the outline below in preparing the narrative.

1. *Abstract* (not to exceed 1 page): Applicants should provide a summary of their proposal and rational plan to carry out the project activities.

2. *Understanding the Project*: Applicants should describe their knowledge of current research conducted in this area, past studies and existing literature. Applicants should state clear study objectives for the current proposed study. Applicants should describe experience with conducting thorough, timely, and comprehensive contact investigations for foreign-born TB cases and their contacts, and the related public health impact.

3. *Methodology and Approach*: Applicants should describe a rational plan to carry out the project activities, including timely methods for the identification of newly diagnosed TB cases and their contacts; methods for medical record review and source case and contact interviews; ability to integrate serologic and non-tuberculous antigen testing portions of the study into existing contact investigation procedures; and ability to conduct targeted location based screening in immigrant communities. Recognition of and plans for overcoming difficulties that may be encountered during the study should be described.

4. *Program Management and Staff experience*: Describe the personnel who will be involved in this project, including information about who will be responsible for general oversight and

management of this project. Include descriptions of the experience required for each proposed staff member to conduct their assigned duties in the proposed project and the projected time commitment from each.

5. *Data Management*: Provide a brief outline of data flow for the proposed project. Provide a description how data abstraction forms will be handled and maintained. Provide a plan for updating data abstraction forms as additional information becomes available over time. Provide a plan for including quality assurance steps that will be used in managing the data.

6. *Budget*: Provide an itemized budget and supporting justification for the first 12 months of the anticipated 2-year project.

F. Submission and Deadline

Submit the original and 2 copies of the application including the CDC Form 0.1246(E). Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm> or in the application kit. On or before January 5, 2001, submit your application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group.

(Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing).

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Your application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Understanding of the Project (20 Points)

The extent to which the applicant demonstrates a clear understanding of the public health impact of conducting thorough, timely, and comprehensive contact investigations for foreign-born TB cases and their contacts as demonstrated through experience, a

knowledge of current research conducted in this area, past studies, existing literature, and the clarity of the proposed study objectives.

2. Methodology and Approach (45 Points)

a. The extent to which the applicant describes a rational plan to carry out the project activities, including timely methods for the identification of newly diagnosed TB cases and their contacts; methods for medical record review and source case and contact interviews; ability to integrate serologic and non-tuberculous antigen testing portions of the study into existing contact investigation procedures; and ability to conduct targeted location based screening in immigrant communities. Recognition of and plans for overcoming difficulties that may be encountered during the study are described.

b. The degree to which the applicant has met 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 the differences when warranted.

(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.

(5) The proposed plan to address language needs during the course of the project.

(6) Delineate the countries of origin from the major foreign-born populations in the projected area.

(7) Describe the language capabilities of staff proposed for this study.

3. Program Management and Staff experience (20 Points)

The proposal clearly describes the (1) qualifications, commitment, and epidemiologic skills and experience of the project director and his/her ability to devote adequate time and effort to provide effective leadership; (2) qualifications and experience of other staff involved in the project to accomplish the proposed activity, and their commitment and time they will devote; (3) successful experience the project director and staff have in managing, coordinating and conducting similar or related projects; (4) a study

coordinator with epidemiologic training and experience who is able to devote at least 50 percent of his or her time to this project; and (5) facilities, space, and equipment necessary for conducting the project.

4. Data Management (10 points)

The proposal clearly describes how data management and data validation will be done.

5. The extent to which the applicant demonstrates continued achievement of the following National TB Program Objectives (5 Points):

a. At least 90 percent of patients with newly diagnosed TB, for whom therapy for 1 year or less is indicated*, will complete therapy within 12 months (*please refer to the definitions in "Reported Tuberculosis in the United States, 1997" for more information). To obtain a copy of this report, you may order through the CDC Website <http://www.cdc.gov/nchstp/tb/> and go to online ordering; or you may contact the Communication and Education Branch, Sherry Hussain, 404-639-8135.

b. At least 85 percent of infected contacts who are started on treatment for latent TB infection will complete therapy.

c. Completeness of RVCT reporting on HIV status for at least 75 percent of all newly reported TB cases age 25-44.

6. Other (Not Scored)

a. Budget

Extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds.

b. Human Subjects

Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Annual progress report, no more than 90 days after the end of the budget period;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this announcement.

AR-1 Human Subjects Requirements
AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-4 HIV/AIDS Confidentiality Provisions

AR-5 HIV Program Review Panel Requirements

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317E of the Public Health Service Act, 42 U.S.C. 247b-6, as amended. The Catalog of Federal Domestic Assistance number is 93.947.

J. Where To Obtain Additional Information

This and other CDC Announcements can be found on the CDC homepage Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

To obtain additional information, contact: Carrie Palumbo, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-2783. Telephone (770) 488-2783. Email address: zri4@cdc.gov.

For program technical assistance, contact: Your program consultant at (404) 639-8125 and from Mary Reichler, Project Officer, Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of TB Elimination, 1600 Clifton Road, Mailstop E-10, Atlanta, Georgia 30333. Telephone: (404) 639-8118. E-Mail Address: mrr3@cdc.gov.

Dated: November 9, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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