

Code of Federal Regulations, Title 21,
Part 56. Institutional Review Boards
(FDA)

Code of Federal Regulations, Title 45,
Part 76. HHS Debarment Regulations

Dated: June 27, 2000.

William F. Raub,

*Deputy Assistant Secretary for Science Policy,
Office of the Assistant Secretary for Planning
and Evaluation, Department of Health and
Human Services.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00095]

Cooperative Agreement for Birth Defects Surveillance, Research, and Prevention Activities; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for the University of South Alabama Birth Defects Surveillance, Research, and Prevention Activities.

B. Eligible Applicants

Single Source: Assistance will be provided only to the University of South Alabama. No other applications are solicited.

This authority is granted under the Consolidated Appropriations Act 2000 (Public Law 106-113), which states: “* * * under section 1509 of the Public Health Service Act * * * \$1,000,000 shall be for the University of South Alabama birth defects monitoring and prevention activities.”

C. Availability of Funds

Approximately \$800,000 is available in FY 2000 to fund this award. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of only 1 year. Funding estimates may change.

D. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: William A. Paradies, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease

Control and Prevention, 2920
Brandywine Road, Room 3000, Atlanta,
GA 30341-4146, Telephone number
(770) 488-2721, Email address:
WParadies@cdc.gov.

For program technical assistance, contact: Larry D. Edmonds, State Services, Birth Defects and Pediatric Genetics Branch, Division of Birth Defects, Child Development, Disability and Health, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop F-45, Atlanta, GA 30341-3724, Telephone number (770) 488-7171, E-mail address: LEdmonds@cdc.gov.

Dated: June 27, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00105]

TB Epidemiologic and Operational Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year 2000 funds for a new cooperative agreement to enhance the capabilities of recipients of state and local tuberculosis (TB) elimination and laboratory agreements to conduct TB epidemiologic and operational research. 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 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: Better understand the changing epidemiology of TB to rebuild the public health infrastructure; identify challenges and opportunities for TB control in an era of changes in health care organizations and delivery; recognize the interdependence of global

TB and TB in the United States; and develop and evaluate new tools for TB diagnosis, treatment and prevention. This new cooperative agreement will be awarded to successful applicants from state and local health agencies to support health department-based investigators with access to 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. Recipients of this award will be expected to conduct site-specific epidemiologic and operational research activities in TB which rely upon the implementation of common, agreed-upon study protocols. Award recipients will be expected to successfully compete for one or more of the specific TB research projects listed below. Eligible applicants may request support for activities under one or more of the following three separate focus areas. See Attachments 1-3 in the application kit for details under each focus area:

1. *Development of Contact Investigation Self-Evaluation Tools:* (See Attachment 1): Assist local TB control programs in building local-level capacity for evaluation of contact investigation processes by providing them with a package of self-evaluation tools. These tools will enable programs to systematically assess contact investigation processes and target programmatic revisions accordingly. The package will include economic evaluation tools to show how program changes will impact resource use and outcomes, thus enabling programs to plan strategically. The package of tools will be pilot tested to ensure usefulness and feasibility. These funds will give state and local health departments the ability to develop practical evaluation tools, based on the CDC’s Recommended Framework for Evaluation, that can be used by local TB programs to use local data to evaluate contact investigation processes. They will also provide for the development of educational support materials to enable local level program staff to understand evaluation principles and conduct self-evaluations.

2. *Improving Contact Investigations in Foreign-Born Populations:* (See Attachment 2) Improve contact identification for foreign-born (FB) TB cases. Improve completeness and timeliness of screening for identified contacts to FB TB cases. Improve the interpretation of screening results for contacts to FB TB cases in [a] the context of screening results for US-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. Improve completion of treatment for latent TB infection for FB 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.

3. *The Unmeasured Impact of the TB Epidemic on TB Programs in Health Departments:* (See Attachment 3) Describe the burden of investigating, providing diagnostic and treatment services, and conducting contact investigations for persons reported as suspect TB cases who are not subsequently verified as a TB case using the public health surveillance case definition or who are verified as a TB case but do not meet the criteria to be included in the area's annual morbidity reported to the national TB surveillance system. These funds will be used to allow state or local public health departments to provide information for public health officials and policy makers to better understand the burden of TB suspects and TB patients who are not included in annual morbidity TB counts. In addition, they will be used to provide a template for approaches to measuring this burden that may be useful in other jurisdictions in the future.

Additional background information and details for each of the three focus areas are provided in Attachments 1–3 in the application kit.

B. Eligible Applicants

Applications for this cooperative agreement award are limited to the official public health agencies of States and territories, or their bona-fide agents that are current recipients of the Tuberculosis Cooperative Awards announced in PA 00001, AND which reported 200 or more TB cases in 1999. These sites are the states of Alabama, Arizona, California, Florida, Georgia, Illinois, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Washington; the cities of Chicago, Houston, Los Angeles, New York, San Diego and San Francisco; and Puerto Rico.

The only additional requirement of eligibility applies to the research activity listed in Attachment 2 for "Improving Contact Investigations in Foreign-Born Populations" which includes a requirement that of the reported 200 or more TB cases in 1999, at least 100 must be among foreign-born persons. Therefore, eligible applicants for this cooperative agreement would be 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, San Diego, and San Francisco.

C. Availability of Funds

Approximately \$1,015,000 is available in FY 2000 to fund approximately 13 awards. See Attachments 1–3 for the specific amount of funds available in each focus area.

It is anticipated that awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change. 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, equipment, or supplies 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 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 audit records to insure 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 Preferences

Funding preferences for awards under this announcement will be given to those applicants who have demonstrated the greatest continued

achievement of the following National TB Program Objectives:

1. At least 90 percent of patients with newly diagnosed TB, for whom therapy for one 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.

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

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

In addition, funding preference will be given to those applicants in areas with a high number of TB cases in foreign-born persons and other high-risk populations (e.g., HIV-infected persons), and to applicants with a high number of culture-positive TB cases reported in urban and rural areas.

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. See Attachments 1–3 for specific Program Requirements for each focus area.

E. Application Content

Submit separate and complete narrative and budget sections for each specific epidemiologic and operations research focus area addressed. For the budget section, submit a separate Form 424A (included in the Application Package) and detailed line-item justification for each focus area project.

Applications for each of the focus areas addressed must be developed in accordance with PHS Form 5161-1 (OMB Number 0937-0189). 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.

Please label each application request clearly. See Attachments 1–3 for specific application content instructions for each focus area.

F. Submission and Deadline

Submit the original and two copies of the application including the PHS Form 5161-1 (OMB Number 0937-0189) on or before July 28, 2000 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

Each application will be evaluated individually against the stated criteria by an independent review group appointed by CDC. Evaluation Criteria instructions specific to each focus area may be found in Attachments 1-3.

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. For a complete description of each, See Attachment IV in the application kit.

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. section 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 on the Internet address <http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements".

To obtain additional information, contact: Carrie Clark, Grants Management Specialist, 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, E-mail address: zri4@cdc.gov

Programmatic technical assistance may be obtained from: Juanita Elder, Division of Tuberculosis Elimination, National Center for Prevention Services, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-10, Atlanta, GA 30333, Telephone (404) 639-8120, Email Address: jlc7@cdc.gov.

Dated: June 27, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Fiscal Year 2000 Competitive Supplemental Funds for Comprehensive STD Prevention Systems: Monitoring Trends in STD Prevalence, Tuberculosis, and HIV Risk Behaviors Among Men Who Have Sex With Men, PA# 99000-H

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease

Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Fiscal Year 2000 Competitive Supplemental Funds for Comprehensive STD Prevention Systems: Monitoring Trends in STD Prevalence, Tuberculosis, and HIV Risk Behaviors among Men who have Sex with Men, PA# 99000-H.

Times and Dates: 8:30 a.m.-9 a.m., August 4, 2000 (Open), 9 a.m.-4:30 p.m., August 4, 2000 (Closed).

Place: Centers for Disease Control and Prevention, Corporate Square, Building 11, Conference Room 2214, Atlanta, Georgia 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 99000-H.

Contact Person for more Information: Beth Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 11 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639-8025, e-mail eow1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 23, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Community-Based Strategies To Increase HIV Testing of Persons at High Risk in Communities of Color, PA# 00100

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis