

in productive employment, and participate in community life.

To assist federal agencies in their review and self-evaluation, we invite the public to submit to us your specific written comments on issues such as barriers in federal law, policy and programs that limit the ability of people of any age who have a disability to achieve the above goals; actions that each of the designated agencies can take to address those barriers, improve the flow of information about community supports or aid in fulfillment of the ADA; and how federal programs can work together in support of enabling an individual with a disability to participate fully in the social and economic life of the community (e.g. health coverage, mental health services, social services, affordable and accessible housing, employment, caregiver support, and other services).

All comments should be submitted to the Department of Health and Human Services at the address noted above. As the coordinating federal agency, the Department will ensure that comments relating to programs administered by any of the other designated federal agencies will be submitted to those agencies for review in conjunction with that agency's review and self-evaluation.

Dated: July 25, 2001.

Tommy G. Thompson,

Secretary, Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

[Program Announcement 01194]

Antiretroviral Drug Sentinel Surveillance To Examine Trends in Prevalence of Drug Resistant Strains of HIV; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program to establish sentinel surveillance methods to examine trends in the prevalence of drug resistant strains of HIV in persons recently infected or recently diagnosed with HIV. This program addresses the "Healthy People 2010" focus area of HIV.

The purpose of the program is to estimate trends in the prevalence of drug resistant strains of HIV in adults by testing HIV positive sera submitted to

state or metropolitan area public health laboratories for HIV testing.

Although the tested population is not representative of the population as a whole, state and local public health laboratories generally conduct diagnostic HIV testing on sera from a section of the population that is broadly similar from year to year. Performing antiretroviral drug resistance (ARVDR) testing on the sera that tested HIV positive should allow an estimate of trends in resistance in persons newly diagnosed with HIV in the geographic area. In addition, Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) testing will be performed on all HIV positive sera and results will be used to describe drug resistance in persons newly infected with HIV. Participants will explore methods to obtain specimens and data that will allow more precise estimates of trends.

Minimal demographic, risk group, and clinical information collected by the HIV/AIDS reporting system will be linked to ARVDR and STARHS results locally without jeopardizing confidentiality.

ARVDR results will be made available to health care providers of the persons whose sera were tested, if the persons tested agree. In future years, participating sites may evaluate the utility of providing baseline (initial pretreatment) antiretroviral resistance test results to clinicians.

The use of sera for antiretroviral resistance testing is still uncommon; however, a satisfactory success rate is thought to be achievable if sera are handled and stored appropriately. This sentinel surveillance network will also provide means to examine the feasibility of routine use of sera for antiretroviral resistance testing. Health departments will be required to establish a quality assurance program for antiretroviral drug resistance testing.

B. Eligible Applicants

Assistance will be provided only to the health departments of States, or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments. In consultation with States, assistance may be provided to political subdivisions of States.

Eligible applicants include health departments meeting these criteria:

1. Having HIV case reporting as of October 1, 2001, and

2. Reporting at least 300 cases of HIV infection in the 12 months ending mid-year 2000, or 300 cases of AIDS (HIV/AIDS Surveillance Report, Dec. 2000, Vol. 12, No. 1).

Funding will be awarded to applicants not currently participating in CDC-supported projects to estimate the prevalence of antiretroviral drug resistance among persons newly infected with HIV. This limitation is imposed to ensure that the gathering of the same or similar data is not already being supported by CDC.

Eligibility is limited to applicants reporting this minimum number of cases of HIV infection yearly (or AIDS cases, if HIV reporting was recently introduced), to insure testing of sufficient numbers of samples to allow a meaningful estimate of the proportion of antiretroviral drug resistant cases. Eligibility is limited to health departments because of the greater likelihood that HIV testing of members of the same subpopulations will take place year after year in health departments, allowing calculation of trends.

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 of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$1,000,000 is available in FY 2001 to fund approximately three awards. It is expected that the average award will be \$330,000, ranging from \$200,000 to \$600,000. It is expected that the awards will begin on or about September 30, 2001 and will be made for a 12-month budget period within a project period of up to five (5) 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.

1. Use of Funds

Funds may not be used to provide direct medical care or prevention case management. Funds may not be used to develop a new HIV infection reporting system for the purpose of this ARVDR project.

2. Funding Preference

Will be given to health departments that report 300 or more newly diagnosed

persons per year and where health department laboratories provide testing for 30% or more of the geographic areas' HIV reports.

D. Program Requirements

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

1. Recipient Activities

a. Develop and administer a suitable consent form for tested individuals and a method for reporting ARVDR results to clinicians of consenting individuals.

b. Collect and appropriately handle serum samples submitted for HIV diagnosis at the public health laboratory. Store and transport samples for STARHS and ARVDR testing to the appropriate laboratory for processing. Report sample collection, handling and storage methods, including the type of anti-coagulant used and the time after blood collection that the serum was separated.

c. If possible, develop a method to identify sera from individuals previously reported as HIV positive to the health department to remove them before they are STARHS tested.

d. Arrange for STARHS testing and genotypic and phenotypic ARVDR testing in the public health laboratory, CDC contract laboratory, or other suitable laboratory. Assure participation in the quality assurance program supported by this activity, including quarterly testing of panels of specimens, if appropriate.

e. Provide results to clinicians of persons whose sera were tested.

f. Capture selected variables from HIV reports for inclusion in the project database.

g. Provide results and share data with other participants, other collaborators in the field, and with CDC.

h. Attend an annual meeting to discuss project activities and methods for data and specimen collection to facilitate more precise estimation of trends.

i. Evaluate the success of the program in providing results to estimate trends in ARVDR in persons newly infected or newly diagnosed with HIV including a plan for the extension of the project in future years, if the program is successful and if funds are available.

j. Develop a research protocol and plans for conducting this research in collaboration with CDC.

2. CDC Activities

1. Assist as needed in the development of a research protocol for

IRB review at all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

2. Provide assistance as needed in the design and conduct of the research and statistical analysis.

3. Provide assistance in training, if requested.

4. Assist as needed in the analysis of the data and the presentation and publication of results.

5. If requested, CDC may provide antiretroviral drug susceptibility testing at a reference laboratory.

6. Provide STARHS testing services at collaborating regional public health laboratories.

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 10 double-spaced pages, printed on one side, with one-inch margins, and unreduced 12 pt. font. All pages should be numbered and indexed. The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget.

F. Submission and Deadline

Submit the original and two copies of CDC 0.1246. Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm

On or before August 31, 2001, submit the 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:

1. Received on or before the deadline date; or

2. 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 which do not meet the criteria in 1. or 2. above will be returned to the applicant.

G. Evaluation Criteria

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

1. Plan (20 points): The quality of the plan to develop and implement the surveillance project. The extent to which the applicant demonstrates:

a. The ability to capture selected variables from HIV reports for inclusion in the project database,

b. The ability to identify, store and transport HIV-positive serum samples of at least half of the number of HIV reports or AIDS cases reported in the 12 months ending mid-year 2000.

2. Objectives (20 points) The extent to which the applicant's proposed objectives are measurable, specific, time-phased, and related to required recipient activities and the program purpose.

3. Methods (25 points) The extent to which the methods proposed are appropriate and feasible to achieve the stated program objectives. This application should describe:

a. How sera will be identified, collected, processed and transported for Antiretroviral Drug Resistance (ARVDR) and Serologic Testing Algorithm for HIV Serconversion (STARHS) testing,

b. The plan to conduct or contract for ARVDR testing the plan for collecting data, and

c. The plan for confidentially linking laboratory tests to the HIV/AIDS reporting system in order to identify persons who have been previously diagnosed and reported to the system.

4. Research Capacity (20 points): The extent to which the applicant demonstrates the knowledge, ability, and experience necessary to facilitate the collection of sera and to provide oversight for data collection and laboratory operations. The application should describe:

a. How the project will be administered,

b. Duties, qualifications, curriculum vitae if available, and time allocation of the proposed staff,

c. The availability of suitable facilities required to conduct this program,

d. In addition, applications will be evaluated on 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: (10 points)

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.

4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

5. Evaluation (15 points): The applicant's ability to evaluate the usefulness of the surveillance program for epidemiologic monitoring and other public health purposes; the extent to which the evaluation plan is appropriate for measuring progress toward program objectives and includes plans to evaluate each aspect of the performance elements outlined in the Recipient Activities; and, the extent to which the applicant documents their willingness and ability to collaborate with CDC in evaluating the success of the pilot project.

6. Budget (reviewed, but not scored): The extent to which the budget is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

7. Human Subjects (reviewed, but not scored): The extent to which the application adequately addresses the requirements of 45 CFR part 46 for the protection of human subjects. 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.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial report 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 program. For a complete description of each, see Attachment I of the announcement 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-6 Patient Care

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-14 Accounting System Requirements

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317 of the Public Health Service Act [42 U.S.C. 241(a) and 247(b)]; 301 (42 U.S.C. 241); 311 (42 U.S.C. 243), as amended. The Catalog of Federal Domestic Assistance number is 93.944.

J. Where To Obtain Additional Information

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

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Julia Valentine, Grants Management Officer, 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) 488-2732, E-mail address: jxv1@cdc.gov.

For program technical assistance, contact: Kenneth A. Clark, M.D., Prevention Services Research Branch, Division of HIV/AIDS Prevention, Surveillance & Epidemiology National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-46, Atlanta, Georgia 30333, Telephone: (404) 639-2042, E-mail address: KClark@cdc.gov.

Dated: July 23, 2001.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01148]

Capacity-Building Assistance (CBA) To Develop and Implement Effective HIV/AIDS Prevention Education Programs for South African Trade Unions; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for capacity-building assistance (CBA) to develop and implement effective HIV/AIDS prevention education programs for South African Trade Unions.

The purpose of the program is to provide financial and programmatic assistance to South African trade unions to develop and implement effective HIV/AIDS prevention education programs.

Note: For this program announcement, the term "capacity-building assistance" means the provision of information, new HIV prevention technologies, consultation, technical services, and training for individuals and organizations to improve the delivery and effectiveness of HIV prevention education.

Business and organized labor have taken an active role in enhancing a partnership between public health and private sector support for HIV prevention. The partnership was initiated as an effort to address workforce education about HIV and its routes of transmission as well as in establishing workplace policies to accommodate HIV in the workplace. This assistance seeks to engage South African trade unions in HIV prevention education and workplace policy development. The goal of the program is to strengthen the capacity of South African trade unions to implement effective HIV/AIDS prevention education programs. The capacity-building assistance program will provide the skills, information and training necessary to:

1. Strengthen the organizational infrastructures that support the delivery of effective HIV prevention services and interventions for union members whose behavior places them at risk for acquiring or transmitting HIV and other STDs;

2. Improve the capacity of trade unions to design, develop, implement and evaluate effective HIV prevention interventions for union members whose