

well as discussion of appropriateness of the sample size (separate evaluation for men and women).

The extent to which the application includes a description of the outcome measures planned including new NAATs for gonorrhea and chlamydia and use of other outcomes (e.g., behavioral outcomes such as condom appeal and correct and consistent use, and process outcomes including quality assurance plans).

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:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. 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.

4. Research Capacity (20 points): The extent to which the application includes a description of the capacity and experience of the research team in prior interventions, including clinical and prevention trials, condom use research, skills-building demonstrations, outcomes research (e.g., laboratory capacity for nucleic acid amplification testing). Curriculum vitae's and position descriptions for key staff and project participants should be included. (Note: Previous experience in testing of condom efficacy in laboratory or in vitro settings would not be considered relevant experience).

5. Evaluation Plan (15 points): The extent to which the application includes a detailed discussion of objectives for the pilot studies, and separate discussion for the intervention phase including enrollment and follow-up objectives. The extent to which plans for enrollment are clearly outlined, and discussion of means to reduce recidivism in follow-up is included. A detailed time-line should also be included.

6. Budget (not scored): The extent to which the budget is reasonable, clearly justified, and consistent with the intent of the announcement.

The 12 month budget should anticipate the organizational and operational needs of the study. The budget should include staff, supplies,

and travel (including two trips per year for two members of the study team to meet with CDC staff and other investigators).

7. Human Subjects (not scored): Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (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.)

#### H. Other Requirements

##### Technical Reporting Requirements

Provide CDC with the original and two copies of:

1. Annual progress reports to be submitted with subsequent continuation applications;

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

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.

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

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the 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 Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-22 Research Integrity

#### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act sections 317 (42 U.S.C. 241(a) and 247b); 301 (42 U.S.C. 241); and 311 (42 U.S.C. 243), as amended. The Catalog of Federal Domestic Assistance number is 93.941.

#### 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 on "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 documentation, business management technical assistance may be obtained from: Annie Camacho, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mailstop E-15, Atlanta, GA 30341-4146, Telephone: (770) 488-2735, Email address: [atc4@cdc.gov](mailto:atc4@cdc.gov).

For program technical assistance, contact: Cassandra Walker, MPH, Acting Deputy Chief, 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, Mailstop E-46, Atlanta, GA 30333, Telephone Number: (404) 639-6191, Email address: [cwalker5@cdc.gov](mailto:cwalker5@cdc.gov).

Dated: July 17, 2001.

**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 01152]

#### Expansion of HIV/AIDS/STI/TB Surveillance and Laboratory Activities in the Federal Democratic Republic of Ethiopia; 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 the expansion of communicable disease surveillance and laboratory activities in the Democratic Republic of Ethiopia.

The purpose of this cooperative agreement is to improve human immunodeficiency virus/Acquired Immuno-Deficiency Syndrome/other sexually transmitted infections/tuberculosis (HIV/AIDS/STI/TB) surveillance and to improve laboratory capacity to assist in the diagnosis of these and other diseases related to HIV infection and transmission in Ethiopia. This will be accomplished by cooperation between CDC and the Ethiopian Health and Nutrition Research Institute (EHNRI) in Addis Ababa, Ethiopia. These collaborative activities could profoundly change the focus and activities of the Ethiopian National AIDS Policy. Most importantly, having a better understanding of the association between specific behaviors and HIV/STI/TB prevalence will likely improve AIDS control programs and prevention efforts in Ethiopia and eventually throughout sub-Saharan Africa.

The U.S. Government seeks to reduce the impact of HIV/AIDS in specific countries within sub-Saharan Africa, Asia, and the Americas through its Leadership and Investment in Fighting an Epidemic (LIFE) initiative. Through this LIFE program, CDC has initiated its Global AIDS Program (GAP) to strengthen capacity and expand activities in the areas of (1) HIV primary prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for surveillance. Targeted countries represent those with the most severe epidemics and the highest number of new infections. They also represent countries where the potential for impact is greatest and where U.S. Government agencies are already active. Ethiopia is one of these targeted countries.

As a key partner in the U.S. Government's LIFE initiative, CDC is working in a collaborative manner with national governments and other agencies to develop programs of assistance to address the HIV/AIDS epidemic in LIFE initiative countries. In particular, CDC's mission in Ethiopia is to work with Ethiopian and international partners to develop and apply effective interventions to prevent HIV infection and associated illness and death from AIDS.

Ethiopia is among the world's countries most adversely affected by the HIV/AIDS epidemic and TB. With an estimated 3 million adults infected with HIV by end of 1999, Ethiopia has the third largest population of HIV-infected persons in the world, accounting for about 9 percent of the world's HIV/AIDS cases. The estimated percent of adults aged 15 to 49 infected with HIV is 10.6

percent, making Ethiopia sixteenth in the world in HIV prevalence. There have been over a million cumulative deaths due to AIDS, with 280,000 occurring in 1999 alone. UNAIDS estimated that 150,000 children are currently living with HIV and that 1.2 million children have been orphaned by AIDS, making Ethiopia third in the number of HIV orphans in the world. The principal routes of HIV transmission are heterosexual and mother-to-infant; HIV and other STIs are closely associated. WHO estimated a TB incidence rate of 260 per 100,000, prevalence rate of 367 per 100,000 and death rate of 82 per 100,000 for Ethiopia in 1997. This represents 156,000 new cases, 221,000 infections and 49,000 deaths for that year. TB cases have been increasing over the years coincident with HIV epidemic; HIV prevalence among TB patients is estimated at 40–50 percent. Data on STIs, however, are scant. These statistics suggest the need for the expansion and improvement of a range of surveillance, care, and prevention activities and services.

Accurate surveillance, as the mainstay of public health programs, provides essential information to focus prevention activities, allocate resources, and monitor effectiveness of programs. Improvement in laboratory capacity to assist in the diagnoses of these and other diseases related to HIV infection and transmission is essential to the HIV/AIDS prevention and control efforts of the Ethiopian people.

#### **B. Eligible Applicants**

Assistance will be provided only to the Ethiopian Health and Nutrition Research Institute (EHNRI), a government entity. No other applications are solicited.

EHNRI is the only appropriate and qualified organization to conduct a specific set of activities supportive of the CDC Global AIDS Program's technical assistance to Ethiopia because:

1. EHNRI is uniquely positioned, in terms of legal authority, ability, and credibility among Ethiopian citizens, to collect crucial data on HIV/AIDS prevalence and incidence, as well as other health information, among Ethiopian citizens.

2. EHNRI already has established mechanisms to access health information, enabling it to immediately become engaged in the activities listed in this announcement.

3. The purpose of the announcement is to build upon the existing framework of health information and activities that EHNRI itself has collected or initiated.

4. EHNRI has been mandated functionally by the Ethiopian

government to serve as the National Reference Laboratory for HIV/STIs/TB, and to coordinate and implement laboratory diagnostic and quality assurance activities related to these diseases including supporting regional laboratories.

#### **C. Availability of Funds**

Approximately \$500,000 is available in FY 2001 to fund this award. It is expected that the award 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 years. Annual funding estimates may change.

Continuation awards within the approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

All requests for funds, including the budget contained in the application, shall be stated in U.S. dollars. Once an award is made, the Department of Health and Human Services (DHHS) will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

#### *Use of Funds*

Funds received from this announcement will not be used for the purchase of antiretroviral drugs for treatment of established HIV infection (with the exception nevirapine in PMTCT cases and with prior written approval), occupational exposures, and non-occupational exposures and will not be used for the purchase of machines and reagents to conduct the necessary laboratory monitoring for patient care.

No funds under this announcement shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

Applicants may contract with other organizations under these cooperative agreements, however, applicants must perform a substantial portion of the activities (including program management and operations and delivery of prevention services) for which funds are requested.

The costs that are generally allowable in grants to domestic organizations are likewise allowable to foreign institutions and international organizations, with the following exception:

*Indirect Costs:* With the exception of the American University, Beirut, the Gorgas Memorial Institute, and the World Health Organization, indirect costs will not be paid (either directly or through a sub-award) to organizations

located outside the territorial limits of the United States or to international organizations regardless of their location.

#### **D. 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 on “Funding” then “Grants and Cooperative Agreements.”

To obtain business management technical assistance, contact: Dorimar Rosado, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention 2920 Brandywine Road, Room 3000 MS-15 Atlanta, GA 30341-4146, Telephone number: (770) 488-2782, e-mail: [dpr7@cdc.gov](mailto:dpr7@cdc.gov)

For program technical assistance, contact: Tadesse Wuhib, MD, MPH CDC Ethiopia, U.S. Embassy, P.O. Box 1014, Entoto Road, Addis Ababa, Ethiopia, Telephone: 251-9-22-00-84 e-mail: [tew7@cdc.gov](mailto:tew7@cdc.gov)

Dated: July 17, 2001.

#### **John L. Williams,**

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

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[Program Announcement 01155]

#### **Improving the Quality of HIV/AIDS Care in the Republic of Zimbabwe; 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 with the University of Zimbabwe (UZ), School of Medicine, Clinical Epidemiology Unit (CEU) for improving the quality of health care services for HIV/AIDS and of related clinical preventive services in the Republic of Zimbabwe.

The U.S. Government seeks to reduce the impact of HIV/AIDS and related conditions in specific countries within sub-Saharan Africa, Asia, and the Americas through its Global AIDS Initiative. Through this initiative, CDC's Global AIDS Program (GAP) aims to strengthen capacity and expand activities in the areas of (1) HIV primary

prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for surveillance. Targeted countries represent those with the most severe epidemics and the highest number of new infections. They also represent countries where the potential for impact is greatest and where U.S. Government agencies are already active. Zimbabwe is one of these targeted countries.

To carry out its activities in these countries, CDC is working in a collaborative manner with national governments, non governmental organizations (NGOs), other national and international agencies to develop programs of assistance to address the HIV/AIDS epidemic. CDC's program of technical assistance to Zimbabwe focuses on several areas including strengthening surveillance and laboratory measures, scaling up promising prevention and care strategies, supporting behavior change communication projects, promoting technology transfer, and other capacity building efforts.

Zimbabwe is experiencing one of the world's most severe AIDS crises that looms as a disaster of unprecedented proportions. Zimbabwe has one of the world's highest HIV prevalence rates among adults, life expectancy has declined from 63 years to 38 years in only a decade, and the proportion of children orphaned by AIDS is expected to reach 35 percent by 2010.

The need for appropriate, quality health care corresponding to the generalized epidemic of HIV/AIDS in Zimbabwe is enormous. Approximately 2 million of the 12 million Zimbabweans are infected with HIV. An estimated 60 percent of hospital inpatients in Zimbabwe suffer from HIV-related conditions, and more than 2,000 deaths per week result from AIDS. A recent burden of disease assessment in Zimbabwe found that nearly 45 percent of all lost disability-adjusted life years (DALYs) in Zimbabwe can be attributed to HIV/AIDS. Tuberculosis rates have increased 10-fold since the mid-1980s, and the World Health Organization (WHO) now lists Zimbabwe as having the highest estimated incidence rates of tuberculosis in the world at more than 500 new cases/100,000 population annually. Despite the tremendous stress on hospitals from the high proportion of patients suffering from HIV-related conditions, the majority of persons diagnosed with or suspected as suffering from HIV/AIDS related conditions in Zimbabwe have in fact been discharged to either self care or systems of “community and home-based care,”

services that may range from quite helpful to being of very little help.

In response to HIV/AIDS, Zimbabwe has taken many positive steps. It was one of the first governments in the world to negotiate a large World Bank loan for AIDS prevention in 1992. In December 1999, the Government of Zimbabwe (GOZ) declared AIDS a national disaster, created a new ministerial-level multi-sectoral National AIDS Council (NAC), announced a new National AIDS Policy, and instituted an “AIDS levy” payroll tax to underwrite improved national AIDS prevention and care services.

The national response has also included many examples of creative programming and successful grassroots initiatives in the face of staggering adversity. Many of these grassroots initiatives were in the domain of home-based care and support for persons living with HIV/AIDS (PLWA). Several excellent evaluations of home-based care for PLWA have been conducted in Zimbabwe at specific points in time. However, no consistent focus or organizational entity has been established that is dedicated to systematically monitoring, evaluating, and attempting to improve the quality of care for HIV/AIDS across all levels of the health system and society, from central hospitals to community and home-based care programs. The AIDS and TB Unit of the Ministry of Health and Child Welfare (MOHCW), which is responsible for public sector health care for HIV/AIDS within the Ministry, has only one physician, who also oversees all health sector aspects of HIV/AIDS prevention and care, as well as all governmental programs for STDs and TB. Therefore, the MOHCW critically needs allied organizations that can assist in coordinating and implementing a broad range of activities to improve quality and coverage of care for HIV/AIDS and related conditions.

The Clinical Epidemiology Unit (CEU) at the University of Zimbabwe (UZ) School of Medicine was established in 1989, after training of an initial cadre of clinical epidemiologists in the United States and Australia. Supported through the International Clinical Epidemiology Network (INCLIN) by the Rockefeller Foundation (until 1992) and by Australia AID (from 1994 to 2001), the UZ CEU has trained 16 persons in clinical epidemiology (including 7 currently in training), 3 in Health Social Science, 3 in Biostatistics, 2 in Health Economics, and 3 in Pharmacoeconomics. This diversity and extent of training in clinical epidemiologic disciplines is superimposed on an underlying further diversity of clinical