

Dated: July 13, 2001.

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*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 01188]

Human Immunodeficiency Virus (HIV) Prevention Intervention Research Studies—Social and Environmental Interventions to Prevent 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 for social and environmental interventions to prevent HIV. This program addresses the "Healthy People 2010" focus area of Human Immunodeficiency Virus (HIV).

The purpose of the program is to design and implement social and environmental interventions to reduce the risk of HIV transmission.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, small, minority, women-owned businesses.

Note: Title 2 of the United States Code, chapter 26, 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 \$400,000 is available in FY 2001 to fund approximately two

awards. It is expected that the average award will be \$200,000, ranging from \$150,000 to \$250,000.

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 two 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.

Use of Funds

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 funds available for HIV Prevention. Funds may not be used to provide direct medical care or prevention case management.

D. Program Requirements

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

1. Recipient Activities

a. Develop a research protocol and plans for conducting this research with appropriate participation of State and local health departments; professional associations, community groups and organizations, especially those with a racial and ethnic minority membership and focus; HIV/AIDS service organizations; and organizations that serve persons increased risk of HIV/AIDS.

b. Promote the development and evaluation of social and environmental interventions for HIV prevention by providing data and ongoing assistance to community planning groups; by disseminating data through publications and presentations; by participating in project planning and implementation meetings; and by reporting ways in which the data have been used to promote public health.

c. Establish procedures to maintain the rights and confidentiality of all study participants. Prior to implementation, this study must be submitted to the local and CDC Institutional Review Boards (IRBs) for review and approval or deferral.

d. Review existing information, research study protocols, and data collection forms.

e. In collaboration with the community, identify opportunities and needs for interventions; assess the acceptability and feasibility of identified interventions; estimate the potential effectiveness of the interventions in preventing infection and disease.

f. Implement the intervention and assess process outcomes.

g. Identify, recruit, obtain informed consent (when appropriate), enroll, and follow an adequate number of study participants as determined by study protocol and the program requirements.

h. Perform data analysis as determined in the study protocol.

2. CDC Activities

a. Provide technical assistance, as needed, in the design and conduct of the research.

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. As needed, assist in designing a data management system.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to follow them in laying out your program plan. The narrative should be no more than 25 pages double-spaced, printed on one side, with one inch margins, and unreduced font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget.

F. Submission and Deadline

Submit the original and five copies of PHS-398 (OMB 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before August 30, 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;

2. Sent on or before the deadline date and received in time for submission to the Special Emphasis Panel. (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 not be considered and 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. Background and Objectives (10 points)

The extent to which the application includes a detailed review of the scientific literature pertinent to the study being proposed, with evidence for the relationship of social and environmental factors to the incidence of HIV. This literature review and a review of conditions in the study community should suggest specific research questions that will guide the research. The extent to which the goals and objectives for the research are clearly stated along with how the intervention would impact one of the underlying factors determining HIV incidence in the community.

2. Site Selection (15 points)

The extent to which the application includes a description of the size and characteristics of the communities proposed for study. The extent to which the application describes the prevalence and estimated incidence of HIV infection in the study community. Includes age, gender, race/ethnicity, and HIV-risks of persons with HIV in the community where the intervention will be implemented; describes the likely acceptability of the intervention by persons in the community. Letters of support from cooperating organizations should be included which detail the nature and extent of such cooperation.

3. Methods (45 points)

Appropriateness of methods for implementing and evaluating the social and environmental interventions to reduce HIV incidence and assessing the potential impact of the intervention within a community or geographic area.

The extent to which the application describes the social-environmental issue that the recipient wants to address, how the potential intervention will influence the issue, and how the intervention might impact on HIV incidence in the study area.

The extent to which the application specifies potential barriers to implementing the intervention and how barriers will be overcome. The potential impact on HIV reduction should be clear. The intervention should be new

and sustainable in the future without ongoing CDC funding.

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 describes the capacity and experience of the research team and includes curriculum vitae and position descriptions for key staff and project participants. The percentage-time commitments, duties, and responsibilities of project personnel should be sufficient to operationalize the proposed methodology.

5. Evaluation Plan (10 points)

The extent to which the application includes time-phased and measurable objectives. The proposed report of research findings should document the process of identifying and implementing the intervention and the acceptability and estimated impact within the community.

6. Budget (not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intent of the announcement.

7. Human Subjects (not scored)

The extent to which the application adequately addresses 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;

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: James Masone, 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) 488-2736, Email address: zft2@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

Dated: July 13, 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 01171]

Expansion of HIV/AIDS Prevention Activities in the Republic of Kenya by Promoting the Establishment of "Free-Standing" or "Stand-Alone" Sites Which Deliver Volunteer Counseling and Testing Services; 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 HIV/AIDS Prevention Activities in the Republic of Kenya.

The purpose of the program is to Promote the establishment of "free-standing" or "stand-alone" sites which deliver voluntary counseling and testing (VCT) services to the Kenyan public in support of the Kenyan CDC Country Plan for HIV/AIDS prevention.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies and international organizations with a minimum of 2 years of experience in managing funds and delivering volunteer counseling and

testing (VCT) service in developing countries in Africa.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code 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 \$1.0 million is available in FY 2001, to fund one award. A similar amount will be available each year during the period of the project. It is expected that the award will begin on or about September 30, 2001 and will be made for a 12-month budget period with a project period of up to five 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.

Use of Funds

All services provided under this announcement will be free to the individuals obtaining the service. The grantee will not collect any fee(s) in association with the services provided.

Antiretroviral Drugs

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.

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 exceptions:

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.

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.

Needle Exchange

No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Funds received from this announcement may not be used for the following: The purchase of machines and reagents to conduct laboratory monitoring for patient care

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under "Recipient Activities", and CDC will be responsible for the activities listed under "CDC Activities"

Recipient Activities

1. Developing and establishing stand-alone VCT sites in key urban areas of Kenya.

a. Identify key urban locations and sites in Kenya appropriate for stand-alone VCT sites, and develop a phased plan for establishment of up to twenty (20) sites by the end of three years.

b. Identify and select local partners (such as but not limited to Non-Government Organizations, NGOs) with the capacity to manage and deliver VCT services at stand-alone sites. (For Example: This may involve selecting one national organization or several regional or local organizations. If necessary, it may involve assisting in the formation of a Kenyan NGO with the specific mandate to provide VCT services, similar to the Ugandan NGO, the AIDS Information Center, which was set up by a consortium of Ugandan and international organizations.)

c. Develop and implement a specific model for service delivery to be uniformly implemented at all sites. This should include hours of operation during evening and weekend hours. Provision of integrated reproductive and HIV related health services at these sites, such as family planning services, the detection and treatment of other sexually transmitted diseases, and TB education and screening is desirable. In addition, on-going services for VCT clients, such as "Post-Test Clubs" and referral networks for care, should be included in the proposal.