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, Atlanta, GA 30341–4146, Telephone number (770) 488–2782, E-mail address: dpr7@cdc.gov.

For program technical assistance, contact: Lawrence H. Marum, M.D., FAAP, MPH, CDC LIFE Initiative P.O. Box 30137, Nairobi, National AIDS/ ASTD Control Programme (NASCOP), P.O. Box 30137, Nairobi, Kenya.

US Mail: Unit 64112, APO, AE 09831–4112, Telephone number: +254–72–721–781 or +254–2–729–549, Fax: +254–2–714–745, E-mail: Lmarum@nairobi.mimcom.net.

Dated: July 17, 2001.

John L. Williams,

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

[FR Doc. 01–18285 Filed 7–20–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01191]

Human Immunodeficiency Virus Prevention Intervention Research Studies—Efficacy of Condom Skills Building Demonstrations for Human Immunodeficiency Virus (HIV)/Sexually Transmitted Disease (STD) Prevention 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 efficacy of condom skills building demonstrations for HIV/ Sexually Transmitted Disease (STD) prevention. This program addresses the ''Healthy People 2010'' focus area of HIV.

The purpose of the program is to study condom use skills-building demonstrations for HIV/STD prevention.

Research Topic

This announcement seeks research applications aimed at developing and evaluating brief (30 minutes or less), condom skills-building interventions that can be conducted with groups of patients in waiting room settings. Refer to Attachment II in the application kit for additional background information on the research topic.

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.

Additional Eligibility Requirements

Eligible applicants must demonstrate:

1. Access to a clinical laboratory capable of conducting urine-based nucleic acid amplification tests (NAATs) for gonorrhea and chlamydia.

2. For this study, the clinic(s) must have at least 180 incident cases of STD over six months among men and at least 180 incident cases of STD over six months among women. STDs among men include gonorrhea, chlamydia, non-gonococcal urethritis (NGU), cervicitis, trichomonas or syphilis. STDs among women include gonorrhea, chlamydia, NGU, cervicitis, trichomonas or syphilis.

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 $700,000 is available in FY 2001 to fund approximately two to three awards. It is expected that the average award will be $240,000 per year, ranging from $190,000 to $290,000. 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 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.

1. 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.

2. Funding Preferences

Funding preference may be given to achieve geographical diversity for condom use skills-building demonstrations in a variety of locations.

D. Program Requirements

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

1. Recipient Activities:

a. Form a Coordinating Committee including all recipients, to design, implement and evaluate project activities, and wherever appropriate, include participation of State and local health departments.

b. Review the literature on (1) new condom technologies and (2) existing brief, waiting room interventions that have been used in STD/HIV prevention and other health-related areas (e.g., family planning, smoking cessation).

c. Based on existing research, conduct formative research that involves (1) brief, pilot studies to help develop a single condom-use skills-building intervention that can be conducted in a waiting room setting, and (2) brief, pilot studies developing new, less costly ways of following study participants for STD outcomes over time. Prior to implementation, pilot study proposals must be submitted to the local and CDC Institutional Review Boards (IRBs) for review and approval or deferral.

d. Based on the results recipient pilot studies, the Coordinating Committee will develop a single research study protocol, quality assurance mechanisms, training tools, data collection instruments and techniques, specimen collection protocols, and data management procedures that will be used across sites.

e. Identify, recruit, obtain informed consent, enroll, and follow for six months an adequate number of study participants as determined by the study protocol.

f. Perform brief data collection as determined by the study protocol. Possible outcomes might include measures such as reported condom use in participants and sex partner(s), and characteristics of sex partners.

g. Collaborate with one or more local clinical laboratories that have the capacity to conduct HIV tests and NAATs for detection of chlamydia and gonorrhea.

h. Conduct data analysis with all collaborators and present and publish research findings.

2. CDC Activities:

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

b. Submit the protocol to the CDC IRB for review and approval.

c. Assist, as needed, in developing specific systems such as a randomization scheme, quality assurance and training procedures, and a data management system, as applicable, a single data set for the collaborators to use for data analysis.

d. Collaborate, as needed, with investigators from the participating research sites to analyze, present and publish research findings.

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 27, 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 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 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 degree to which the application includes a detailed review of the scientific and other literature pertinent to new condom technologies and condom skills-building and other single session skills-building demonstrations for use in waiting room settings. The literature review should discuss the strengths and limitations of previous research in this area, including discussion of pros and cons of various research designs. The degree to which the application also includes one or more potential condom skills-building demonstrations from the literature that are brief (30 minutes or less), feasible for use in waiting room settings, and acceptable for both men and women. Potential control conditions should also be described. Presentation of data on acceptability of the proposed intervention based on previous research, focus groups, or pilot studies would enhance the application.

2. Site selection (25 points): The extent to which the application includes a description of the clinic in which the demonstrations are anticipated to be conducted, including waiting room characteristics, size of the clinic population (e.g., number of men and women aged 15–34 years seen each month), and STD (gonorrhea, chlamydia, syphilis, NGU, cervicitis, or trichomonas) prevalence among men and women. Sufficient patient enrollment is estimated to be 60 to 80 STD-infected clients aged 15–34 years per month, of which at least 30 are women. Participant refusal should be taken into account. Previous research in STD clinic settings indicates that no more than 50% of eligible participants will enroll in a study with long-term follow-up for STD infection. Enrollment rates are typically lower for men than women; The extent to which the application also includes a description of the collaborating laboratory and its capabilities, including experience with new NAATs. The extent to which the application includes a description of the proposed investigators and their previous research in conducting brief, group interventions aimed at STD/HIV prevention, including condom-based interventions. Letters of support from cooperating organizations, including clinic, laboratory, and (if applicable) health department directors and other participating staff should be included, and these should detail the nature and extent of such cooperation. The letter from the clinic director should specifically address patient volume, STD control, and the number of patients that potentially could be enrolled in a specific time period.

3. Methods (30 points): The extent to which the goals and objectives for the proposed research study are clearly stated and include a detailed discussion of the intervention(s) and control conditions, description of an appropriate study design, estimated sample size for men and women, and follow-up requirements using existing STD information.

The extent to which the application includes a detailed description of: (a) One or more brief, waiting room interventions that involve condom use demonstrations that could potentially be studied; and (b) a control condition that could potentially be used.

The extent to which the proposed intervention condition(s) includes supporting data on: The appropriateness of the intervention for the clinic and for the intended audience (including men and women), brevity (preferably less than 30 minutes), use of new condom technologies and a variety of condom types, use of appropriate and effective intervention techniques (e.g., role play scenarios, skills-building demonstrations as opposed to information-only approaches), feasibility and appropriateness of the intervention for waiting room settings, simplicity to allow existing staff to conduct the intervention, ease of the intervention in fitting in with current waiting room and clinic patterns, and discussion about how the proposed intervention(s) could be transferred to other high risk populations.

The extent to which the application identifies potential barriers to implementing the intervention and how these will be overcome.

The extent to which the application includes detailed methods for implementing and evaluating the intervention using a controlled design that minimizes bias (e.g., randomized controlled trial using group-level or individual randomization). Sample size calculations should be presented, as

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.

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 17, 2001.

John L. Williams,

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

[FR Doc. 01–18286 Filed 7–20–01; 8:45 am]

BILLING CODE 4163–18–P

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.