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. Potential barriers to implementing the intervention and how these will be overcome should be discussed.

The application should also include 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). In addition, the application should include description of the outcome measures planned including urine-based, nucleic acid amplification tests 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). (25 points)

In addition, (5 points)

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 experience of the applicant in similar clinical interventions, condom research, and HIV/STD prevention research, and availability of qualified and experienced personnel.

The application should include 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 applicant includes time-phased and measurable objectives for all phases of the proposed study (formative, intervention, and evaluation phases).

The application should include a detailed discussion of objectives for the pilot studies, and separate discussion for the intervention phase including enrollment and follow-up objectives. Clear plans for enrollment should be outlined, and discussion of means to reduce recidivism in follow-up should be 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 up to 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 Title 45 CFR Part 46 for the protection of human subjects?

Dated: July 24, 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

[Announcement Number 01190]

Human Immunodeficiency Virus (HIV) Prevention Intervention Research Studies—Prevention for HIV-Positive Persons; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2001 funds for HIV Intervention Research Studies—Prevention for HIV-Positive Persons was published in the **Federal Register** on July 19, 2001, [Vol. 66, No. 139, pages 37694–37696]. The notice is amended as follows:

On page 37694, First Column, under section B. Eligible Applicants, add the following paragraph immediately following paragraph number one:

Additional Eligibility Criteria

Eligible applicants must have:

1. A minimum of three participating clinics in the project. Provide evidence of this by including letters from each participating clinic signed by the responsible facility administrator; and

2. Each participating clinic must be currently serving a minimum of 300 HIV infected persons. Provide a statement signed by the responsible facility administrator certifying the number of HIV infected persons served.

On page 37695, Third Column, Under Section G. Evaluation Criteria, change to read:

The quality of each application will be evaluated individually against the following criteria by an objective review group appointed by CDC.

1. *Background, understanding of problem and objectives (10 points):*

a. Demonstrates knowledge of literature pertinent to the proposed program and its goals. Demonstrates an understanding of how prevention models developed for high-risk individuals should be adapted, as suggested by theory or research, to customize the service for HIV infected persons. (5 points)

b. Provides a compelling argument for justifying the care setting in which program will be implemented (patient load, lack of available prevention services, etc.). (5 points)

2. Demonstrating the quality of proposed prevention program. (15 points)

a. Exceeds the minimum number of 900 clients served by the clinics participating in the study (minimum three (3) clinics X minimum 300 clients per clinic). One point will be given for every 200 additional HIV infected clients, up to a maximum of 5 points. (5 points)

b. Demonstrates adequacy of proposed program to address the purpose stated in the background section: reduction in unprotected sex and/or needle sharing with HIV negative partners and partners of unknown status. (Disclosure of serostatus and adherence to therapy are acceptable but not required as additional outcomes). (5 points)

c. Presents a program which adequately incorporates into the prevention model organizational and personnel factors which accelerate adoption and proper implementation by the care organizations specified in the application. (5 points)

3. Demonstrating the appropriateness of research design to evaluate the proposed program. (35 points)

a. Presents an overall research design which can generate reasonably certain conclusions about the effects of the proposed program; and which includes appropriate design elements such as: outcome measures taken at pre-intervention, post-intervention and follow-up; process measures; control or comparison group(s). (20 points)

b. Presents reliable and valid measures to gauge effectiveness at three levels: Organizational adoption (ability and willingness of the service organization to provide sustained support); adoption by care personnel (acceptance and use by the individual service providers); reduction in risk behaviors by clients. (10 points)

In addition, (5 points)

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. Demonstrating the ability to implement the intervention and the research design. (40 points)

a. Demonstrates the extent to which the applicant has the necessary skills and resources needed for both program and research design implementation. In cases where a collaboration is necessary between different organizations, demonstrates the ability to put together the collaboration necessary for adequately implementing the program and the research design. Demonstrates the degree of commitment from non-lead organizations to the project and explains how the lead organization intends to maintain this commitment. Letters of support from all collaborating organizations are the required minimum.(10 points)

b. Identifies the technical assistance and training needs required for the proper implementation of the prevention service and the research protocol, and presents a plan that ensures that these needs will be met. (5 points)

c. Specifies methods for careful verification that the proposed intervention is actually being implemented. (5 points)

d. Specifies a plan for tracking participants and ensuring successful follow-up. (5 points)

e. Presents a plan for carrying out the program and research activities. (5 points)

f. Demonstrates experience and expertise in conducting similar prevention programs and research. (10 points)

5. *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 up to two members of the study team to meet with CDC staff and other investigators).

6. *Human Subjects (not scored):* Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

Dated: July 24, 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 01186]

Landmine and War-Related Trauma Awareness Program; 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 develop, implement, and evaluate diverse activities addressing landmine and war-related trauma (physical injury and mental health) directly and indirectly caused by war, including the evaluation of mine awareness programs in current and former conflict-affected countries. This program addresses the ''Healthy People 2010'' focus areas of Injury and Violence Prevention and Environmental Health.

The purpose of the program is to establish a better understanding of the burden of landmine and other war-related trauma, particularly on women and children globally; to evaluate, using existing data, mine awareness and other war-associated injury prevention programs; and to develop and distribute best practices applicable to mine awareness and other conflict-related injury prevention programs.

No human subjects research may be conducted under this program announcement.

B. Eligible Applicant

Assistance will be provided only to The United Nations Children's Fund (UNICEF). No other applications are solicited.

UNICEF is the most appropriate and qualified organization for conducting activities under this program because:

UNICEF is the United Nations organization tasked with taking the lead on mine awareness. UNICEF is also the United Nations organization tasked with the protection of health and human rights of women and children. Therefore, UNICEF provides a unique opportunity to evaluate current mine awareness and other war-associated injury prevention programs.

UNICEF has a singularly high level of expertise and experience in mine awareness programs and working with women and children affected by conflict.

UNICEF is the leader in the international community as a provider of data about and support to women and children affected by war, giving it the resources and contacts to implement this program.

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 $175,000 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 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.

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: Sharron Orum, 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) 488–2716, Email address: SPO2@cdc.gov.

For program technical assistance, contact: Marilyn DiSirio, International Emergency and Refugee Health Branch, Division of Emergency and Environmental Health Services, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway (F–48), Atlanta, GA 30341, Telephone number: (770) 488–4024, Email address: mdisirio@cdc.gov.

Dated: July 24, 2001.

John L. Williams,

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

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