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):* Experience in other similar research collaboration with State and local health departments and availability of qualified and experienced personnel.

The application should describe the capacity and experience of the research team and should include curriculum vitae and position descriptions for key staff. The percentage-time commitments, duties, and responsibilities of project personnel and involvement of state and local health department personnel should be sufficient to operationalize the proposed methodology. Letters of support from key collaborators, community groups, State and local health departments, should be included. The application should document that there is sufficient space available in the ambulatory care clinic or emergency room for the addition of the testing program.

5. *Sustainability of the intervention (15 points):* Evidence of the health department and community planning group's commitment to sustain this program beyond the end of the project period and funding support, if it finds more infected persons at a lower cost than other existing outreach programs. Evidence includes letters of support from the community planning group and the health department, and the applicant's plan for encouraging the continuation of program activities.

6. *Evaluation Plan (10 points):* Appropriateness and comprehensiveness of:

a. The schedule for accomplishing the activities of the research;

b. An evaluation plan that identifies methods and instruments for evaluating progress in implementing the research objectives; and

c. A proposal to complete and submit for publication, a report of research findings.

The application should include time-phased and measurable objectives. The proposed report of research findings should document the increase in number of persons tested, the number of new infections identified, and the number of persons who access treatment.

7. *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).

8. *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).

[FR Doc. 01–18864 Filed 7–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 01191]

Human Immunodeficiency Virus Prevention Intervention Research Studies—Efficacy of Condom Skills Building; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2001 funds for Human Immunodeficiency Virus Prevention Intervention Research Studies—Efficacy of Condom Skills Building was published in the **Federal Register** on July 23, 2001, (Vol. 66, No. 141, pages 38283–38285). The notice is amended as follows:

On page 38284, Second Column, Under Section G. Evaluation Criteria, change to read:

The quality of 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 applicant demonstrates knowledge in the area of condom use and skills-building demonstrations and understands the evaluation methodology (i.e., randomized controlled trial) that would be used in the project.

The application should include 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 application should also include 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 applicant demonstrates adequate capacity to conduct the research study, including:

a. Access to one or two existing clinical settings with a waiting room;

b. Sufficient patient volume of ''new'' (*i.e.,* not follow-up) visits among both men and women who are infected with either gonorrhea or chlamydia to allow evaluation of the intervention with urine-based nucleic acid amplification tests; and

c. Access to an experienced laboratory capable of conducting urine-based nucleic acid amplification test for detection of gonorrhea and chlamydia.

The application should include 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 application should also include a description of the collaborating laboratory and its capabilities, including experience with new urine-based nucleic acid amplification technologies. The application should include 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 appropriateness of the methods presented for developing, implementing, and evaluating the intervention.

The goals and objectives for the proposed research study should be clearly stated and should 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 application should include 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 proposed intervention condition(s) should include 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. 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.