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 goals and objectives for the research should be 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): Demonstrate high prevalence of HIV or AIDS in the study area. Demonstrate ability to work in the community or communities.

The application should include a description of the size and characteristics of the communities proposed for study. Describe the prevalence and estimated incidence of HIV infection in the study community. Include the age, gender, race/ethnicity, and HIV-risks of persons with HIV in the community where the intervention will be implemented. Describe 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 application should describe 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. It should specify 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. (40 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): Experience in similar social interventions, human rights evaluations, and HIV prevention research; and availability of qualified and experienced personnel.

The application should describe the capacity and experience of the research team and should include curriculum vitaes 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. Letters of support from key collaborators and community groups should be included.

5. 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 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.

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 four 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).

[FR Doc. 01–18861 Filed 7–27–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 01187]

Human Immunodeficiency Virus (HIV) Prevention Intervention Research Studies—Routinely Recommending HIV and Sexually Transmitted Disease (STD) Counseling and Testing in Ambulatory Care Clinics and Emergency Rooms; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2001 funds for HIV Intervention Research Studies—Routinely Recommending HIV and STD Counseling and Testing in Ambulatory Care Clinics and Emergency Rooms was published in the **Federal Register** on July 20, 2001, (Vol. 66, No. 140, pages 37966–37969). The notice is amended as follows:

On page 37967, First Column, under Section B. Eligible Applicants, add the following paragraph immediately following paragraph number one:

Additional Eligibility Criteria

1. Demonstrate ability to do testing for chlamydia, gonorrhea, and HIV by including a letter from a contract laboratory or facility administrator.

2. Provide evidence of adequate available space for the testing program in the form of a letter from the responsible facility administrator.

3. Provide evidence that at least 500 HIV-infected persons per year visit the ambulatory care facility or emergency room.

On page 37967, 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 independent review group appointed by CDC.

1. *Background and Objectives (10 points):* Demonstrate that the proposed study will identify persons who do not know they are infected with HIV.

The application should include:

a. A detailed review of the scientific literature pertinent to testing in ambulatory care clinics and emergency rooms;

b. Clearly stated goals and objectives for the research; and

c. A description of how the intervention would impact HIV and STD prevention in the community.

2. *Site Selection (15 points):* Demonstrate high prevalence of HIV or AIDS in the study area.

The application should include a description of:

a. The current magnitude and characteristics of the HIV epidemic;

b. STD disease burden;

c. The number of persons served by the clinics; and

d. The expected number of newly-identified HIV infections that will be detected.

Letters of support from cooperating organizations should be included which clearly describe the nature and extent of such cooperation.

3. *Methods (30 points):* Appropriateness of methods for implementing and evaluating the testing program.

The application should describe the potential intervention and how it might impact on HIV and STD incidence in the study area. It should specify potential barriers to implementing the intervention and how they will be overcome. The methods for assessing the increase in number of persons tested, as well as the number of infected persons identified and successfully referred for treatment, should also be addressed. (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):* 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).

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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