DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99155]

Non-Invasive Diagnosis of Viral and Bacterial Sexually Transmitted Diseases (STDs) in Sexually Assaulted Female Adolescents and Children; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for non-invasive diagnosis of viral and bacterial sexually transmitted diseases (STDs) in sexually assaulted female adolescents and children. This program addresses the ''Healthy People 2000'' priority area of Immunization and Infectious Diseases. The purpose of the program is to assist Child Protection and Child Abuse and Assault Intervention Centers (CPCs) in conducting investigations to achieve the project goals to (1) evaluate use of non-invasive specimens with less discomfort for the patient, and greater ease of storage, transport and sensitivity, for diagnosis of STDs; (2) study the epidemiology of viral STDs among sexually abused and non-abused children and adolescents, specifically exploring the significance of infection with various human papilloma virus (HPV) types and herpes simplex virus (HSV–2), and; (3) determine usefulness, if any, of non-invasive assays for viral STDs in increasing certainty of abuse assessment. These funds would enable CPCs to evaluate, in real world settings, the modalities in the diagnosis of STDs and their role in the determination, in children, that sexual abuse has taken place.

B. Eligible Applicants

Assistance will be provided only to recognized CPCs or their bona fide agents. For the purpose of this announcement, CPCs are limited to facilities, including emergency rooms, urgent care facilities, and child protection services that examine at least 300 patients, female children (aged 3–13 years of age) and adolescents (13 years 1 day to 20 years of age), for possible sexual abuse or assault. Applicants need to be facilities that obtain laboratory diagnostic testing for STDs as part of these examinations.

Note: Pub. L. 104–65 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 $80,000 is available in FY 1999, to fund one award. It is expected that the average award will be $80,000. It is expected that the award will begin on or about September 30, 1999 and will be made for a 12-month budget period within a project period of up to five years. The funding estimate 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. 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. Design a protocol to:

1. Evaluate the sensitivity and specificity of urine nucleic acid amplification tests for *C. trachomatis* and *N. gonorrhoeae* relative to the ''gold standard'' of cultures performed at the laboratory(ies) at which the applicant normally has its diagnostic tests performed. A ''gold standard'' is the test to which experimental tests will be compared;

2. Perform routine diagnostic tests on children and adolescents in whom sexual abuse or assault is suspected, including vaginal or cervical cultures for *C. trachomatis* and *N. gonorrhoeae;* HSV cultures and/or other tests as judged appropriate by applicant in a Clinical Laboratory Improvement Act (CLIA) approved laboratory;

3. Evaluate the significance relative to certainty of sexual abuse, of finding antibody to HSV 2 or HPV by serologic tests.

4. Evaluate the significance, by HPV type, of genital warts, relative to certainty of sexual abuse.

b. Conduct epidemiologic studies to assess certainty of abuse in children, by whether they present with each of a variety of common complaints related to sexual abuse, including genital lesions, witnessed or reported abuse, etc.

c. Analyze and summarize data from these studies in collaboration with CDC and other funded applicants for presentation, publication, and revision of current child sexual abuse and adolescent sexual assault guidelines.

2. CDC Activities

a. Provide consultation and scientific and technical assistance in designing the protocol, collecting study specimens, and conducting the studies.

b. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Conduct experimental tests not performed by applicant (including HPV and HSV 2 serologic tests, *C. trachomatis* and *N. gonorrhoeae* urine nucleic acid amplification tests, and type-specific HPV tests for genital warts), blinded to the certainty of abuse.

d. Assist in analysis and interpretation of data and participate in the timely dissemination of findings and information stemming from these studies.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than [12] double-spaced pages, printed on one side, with one-inch margins, and unreduced font.

F. Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are available in the application kit. On or before August 15, 1999, 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:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received prior to the submission to the review 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: Applications which do not meet the criteria in (a) or (b) above are considered late applications, 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

The extent to which the applicant in the Background section demonstrates a clear understanding of this program and its main goals. The extent to which applicant demonstrates a clear understanding of the requirements, responsibilities, problems, constraints and complexities that may be encountered in conducting this study. (10 points).

2. Technical Approach

The extent to which the applicant defined clearly the population base from which the participants will be enrolled. The extent to which the applicant defines a population base for the study that is appropriate in size and diversity, with high enough number of children and adolescents presenting with possible, probable or certain abuse or assault, and with high enough prevalence of the infections of interest for the accomplishment of proposed activities. The extent to which the applicant clearly describes a population served in 1998, how they came to the attention of the CPC, how the decision was made to test or not test for STDs, the outcome of these laboratory tests and how the determination of certainty of abuse was made. (20 points).

3. Capacity

The extent to which the applicant demonstrates its capacity and ability to maintain a sufficient number of female children possibly, probably or definitely abused by demonstrating referral sources, and collaboration in past or on-going studies. The extent to which the applicant demonstrates its ability to develop and maintain strong cooperative relationships with various public and private local and regional medical, public health, community-based and academic organizations. The extent to which applicant demonstrates its ability to collaborate with other public and private organizations for conducting public health research projects and/or activities related to sexual abuse and/or STDs in children and adolescents. The extent to which applicant provides letters of support from non-applicant participating agencies, institutions, organizations, individuals, consultants, etc., indicating their willingness to participate, as represented in applicant's operational plan, in conducting the study. (25 points).

4. Operational Plan

a. The extent to which the applicant's proposed plan for conducting the study and the protocol is detailed and clearly describes the proposed organizational and operating structure/procedures and clearly identifies the roles and responsibilities of all participating agencies, organizations, institutions, and individuals. The extent to which the applicant describes plans for conducting the project. The extent to which the applicant's plan addresses all Recipient Activities listed in this announcement and appears feasible and capable of accomplishing the purpose of the program. The extent to which the applicant covers Recipients Activities explained in this announcement (15 points).

b. The extent to which the applicant proposal demonstrates support from applicant's institution and consistency with the intent of the RFA, its feasibility, quality of methodology and documentation of plans for recruitment and enrollment of study participants (10 points).

c. 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:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process for study establishing partnerships with community(ies) and recognition of mutual benefits. (5 points).

5. Personnel Qualification and Management Plan

The extent to which the applicant identifies its own professional and support staff, and professional and support staff from other agencies, institutions, and organizations, that have the experience, authority and willingness to carry out recipient activities as evidenced by job descriptions, curriculum vitae, organizational charts, etc. The extent to which the applicant describes an approach to maintain a sufficiently flexible staffing pattern. (10 points).

6. Evaluation Plan

The extent to which applicant provides an adequate evaluation plan, which includes time-based and outcome-based criteria. The quality of the proposed plan for monitoring accomplishments. The quality of the proposed evaluation plan for monitoring progress in achieving the purpose and overall goals of this program. (5 points).

7. Budget

The extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of the awarded funds. The extent to which both Federal and non-Federal (e.g., state funding) contributions are presented. (Not scored).

8. Human Subjects

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? (Not scored).

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports (semiannual);

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, 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.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Public Health Service Act, sections 301(a) (42 U.S.C. 241(a)) and 317(k)(2) (42 U.S.C. 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

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, 99155.

See also the CDC home page on the Internet web site at http://www.cdc.gov and the program and grants office web site for additional funding opportunities and electronic versions of all necessary forms (www.cdc.gov/od/pgo/forminfo.htm).

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone Number: 770–488–2753, Email Address: gcg4@cdc.gov.

For program technical assistance, contact: Dr. Consuelo Beck-Sague, Office of Minority Health, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone Number: 404–639–3467, Email Address: cmb1@cdc.gov.

Dated: June 15, 1999.

Henry S. Cassell,

Acting 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 99090]

Intervention Research Addressing the Primary and Secondary Prevention Needs of HIV-Seropositive Injection Drug Users Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) announce the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to support intervention research on the primary and secondary prevention needs of HIV-seropositive injection drug users (IDUs). This announcement addresses the ''Healthy People 2000'' priority area Human Immunodeficiency Virus (HIV) Infection.

The purpose of this announcement is to support intervention research for HIV-seropositive IDUs that leads to the development of effective, feasible, and sustainable interventions having three goals: (1) To prevent HIV transmission due to high risk sexual and drug injection behaviors; (2) to increase access to, use of, and maintenance in primary health care; and (3) to increase access to, use of, and adherence to HIV treatments, including prophylaxis to prevent opportunistic infections.

Consistent with this purpose, funding under this program will support: (1) One year for intervention refinement and piloting of intervention strategies and components, in collaboration with other funded sites; (2) three years for a multi-site randomized controlled trial to test behavioral/biomedical interventions and strategies for this population; and (3) one year for data analysis and dissemination of research findings.

The intervention proposed for the trial must be based on behavioral theory as well as: (1) Prior research on sexual and drug injection practices among IDUs that lead to HIV/STD risk; and (2) prior research or research data on either adherence to HIV treatment or access to health care. The ultimate goal of this research is the identification of successful intervention strategies for HIV-seropositive IDUs, with an emphasis on IDUs newly diagnosed as HIV seropositive (within the past three years). It is expected that these strategies will integrate behavioral and biomedical approaches and will lead to models that are appropriate for implementation in community settings (e.g., local health departments, community-based organizations, health maintenance organizations) and that are suitable for replication in other communities.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, state and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104–65 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 $2,000,000 is available in FY 1999 to fund three to five awards. It is expected that the average award for the first year will be $500,000. An application requesting greater than $600,000, including indirect costs, in year one will not be considered for review and will be returned to the applicant.

Awards are expected to begin on or about **September 30, 1999**. Awards will be made for a 12-month budget period within a total project period of up to five years. It is anticipated that increased funding may be available in years 2–4 to support the randomized controlled trial and in year 5 to support data analysis and dissemination of research findings. Funding estimates may vary and are subject to change based on the availability of funds.

Continuation awards within the project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Funding Preference

In order to promote research and interventions that address the needs of diverse regions of the United States, geographic diversity may be a factor considered in funding decisions. The recruitment area for funded applicants may not overlap. In addition, applicants must demonstrate that intervention programs and research studies for HIV-seropositive IDUs that are currently being conducted in the applicant's catchment area will not jeopardize the success of the proposed research.

D. Program Requirements

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

1. Recipient Activities

a. Refine and pilot test intervention strategies and components.

b. Develop plans for active collaboration during the entire project with local health departments, medical service providers, members of the affected population, their service providers, and community organizations.

c. Develop research protocols and data collection instruments appropriate to conduct a multi-site randomized controlled intervention trial.

d. Develop plans to collect prospective cost data for the intervention to allow estimates of the