I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 318 and 318A of the Public Health Service Act, 42 U.S.C. sections 247c and 247c–1, as amended. The Catalog of Federal Domestic Assistance number is 93.941.

J. Where To Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Kathy Raible, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE, Room 300, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6649, or via email at: <kcr8@cdc.gov>.

Programmatic technical assistance may be obtained from Julie Schillinger, MD, MSc, Division of STD Prevention, NCHSTP, CDC, 1600 Clifton Road; Mailstop E–02, Atlanta, Georgia 30333, telephone (404) 639–8368, or via email at: <jus8@cdc.gov>.

This and other CDC announcements can be found on the CDC homepage (http://www.cdc.gov) under the ''Funding'' section. For your convenience, you may be able to retrieve a copy of the PHS Form 398 from (http://www.nih.gov/grants/funding/phs398/phs398.html).

Please Refer to Announcement Number 98094 When Requesting Information and Submitting an Application.

CDC will not send application kits by facsimile or express mail.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: July 2, 1998.

John L. Williams,

Director, Procurement and Grants Office.

[FR Doc. 98–18199 Filed 7–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 98097]

Behavioral Intervention Research on The Prevention of Sexual Transmission of HIV By HIV-Seropositive Men Who Have Sex With Men

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for the prevention of HIV transmission by HIV-seropositive men. This program addresses the ''Healthy People 2000'' priority area Human Immunodeficiency Virus (HIV) Infection.

The purpose of this program is to support research evaluating the outcome of interventions based on formative research that reduce the spread of HIV by men who have sex with men who know they are HIV seropositive. Consistent with this goal, funding under this program will support a randomized controlled trial to evaluate the effectiveness of intervention activities designed to motivate and support HIV-seropositive men who have sex with men in sustaining sexual practices that reduce the risk and prevent HIV transmission to partners who are sero-negative or of unknown serostatus.

The intervention proposed for the trial must be based on formative research, behavioral theory, and results of prior pilot evaluations. Because of the differential impact of HIV on men of color, both the prior formative research and the proposed intervention trial must be based on samples in which the majority of participants are men of color. The ultimate goal of this research is the identification of successful intervention strategies for HIV-seropositive men who have sex with men 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 community settings.

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. 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.

1. Funding Preference

This announcement is for behavioral intervention studies that build upon formative research findings regarding transmission risk among HIV-seropositive men who have sex with men. Because of the differential impact of HIV among men of color, preference will be given to applicants with documented ability to recruit research samples of HIV-seropositive men who have sex with men in which the majority of participants are men of color. In order to ensure the success of the proposed project, it is essential that applicants have access to sufficient numbers of HIV-seropositive men who have sex with men. Therefore, preference will also be given to applications from metropolitan areas having a 1997 AIDS incidence rate exceeding 50 per 100,000.

2. Funding Priorities

This announcement is for behavioral intervention studies that build upon research findings regarding transmission risk among HIV-seropositive men who have sex with men. This announcement will support behavioral intervention studies that build upon research findings regarding transmission risk among HIV-seropositive men from formative studies. This new research initiative will lead to the development of effective, feasible, and sustainable interventions that reduce the spread of HIV by men who know they are HIV seropositive. Consistent with this goal, funding under this program will support a randomized controlled trial to evaluate the effectiveness of intervention activities designed to motivate and support HIV-seropositive men who have sex with men in sustaining sexual practices that reduce the risk and prevent HIV transmission to partners who are sero-negative or of unknown serostatus.

C. Availability of Funds

Approximately $800,000 is available in FY 1998 to fund two awards. It is expected that the average award will be $400,000. Awards are expected to begin on or about September 30, 1998, and

will be made for a 12-month budget period within a project period of up to three years. The funding estimate is subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress 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 identified under Recipient Activities below and CDC will be responsible for the activities identified under CDC Activities below:

Recipient Activities

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

b. Establish procedures to maintain the rights and confidentiality of all study participants, including review of research activities by recipient's and CDC's Institutional Review Board (IRB).

c. Identify, recruit, obtain informed consent, and enroll an adequate number of research participants according to procedures specified in the study protocol.

d. Conduct intervention sessions, interviews, and other assessments according to the research protocol.

e. Summarize data and conduct data analyses.

f. Disseminate research findings in peer-reviewed journals and at professional meetings.

CDC Activities

a. Provide scientific and technical assistance in the design and development of the research, and evaluation protocols, selection of measures and instruments, operational plans and objectives, and data analysis strategies.

b. Provide scientific and technical coordination of the general operation of the research project, including data management support.

c. Participate in the analysis of data gathered from program activities and the reporting of results.

d. Conduct site visits to assess program progress.

e. Assist in the development of a research protocol for Institutional Review Board (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.

E. Application Content

The application may not exceed 30 double-spaced pages in length, excluding appendices (The appendices are the appropriate location for intervention protocols, references, and memoranda of agreement documenting collaboration with other agencies). Provide a one-page abstract of the proposal. Number all pages clearly and sequentially and include a complete index to the application and its appendices. Submit the original and each copy of the application UNSTAPLED and UNBOUND. Print all material, double spaced, in a 12-point or larger font on 8½″ by 11″ paper, with at least 1″ margins and printed on one side only.

Use the following outline.

1. Ability To Recruit HIV-Seropositive Men

a. Describe methods previously used to recruit community-based research samples of HIV seropositive men who have sex with men;

b. Describe the differential success of various recruitment strategies;

c. Describe the ethnic/racial background of participants in the research sample(s).

2. Formative Research With HIV-Seropositive Men

a. Describe methods used to collect qualitative and quantitative formative data regarding the HIV transmission risk and its determinants among HIV-seropositive men who have sex with men;

b. Summarize findings from the formative research phase, highlighting those with special relevance for the design of HIV prevention efforts;

c. Attach copies of all abstracts, presentations, and manuscripts that describe findings from the formative research phase;

d. Discuss ways in which HIV-seropositive men and their advocates or service providers were involved in the formative research phase.

3. Intervention Research Plan

a. Describe the hypotheses and outcomes that will be addressed as part of the intervention trial;

b. Describe the characteristics of HIV-seropositive men who have sex with men in the proposed study population and define the specific subgroups of HIV-seropositive men that will be the primary focus of the proposed research. Using available data, provide a rationale for any focus on specific population subgroups. Document ability to recruit sufficient numbers of men from the proposed target population;

c. Describe the research design and methods that will be employed in the intervention trial. Include information about randomization procedures, statistical power to detect hypothesized differences, primary (behavioral and biological) and secondary (relevant mediating variables) outcome measures, the reliability and validity of measures that will be used, and procedures for maximizing external and internal validity (e.g., sampling strategies and retention procedures, respectively);

d. Provide a detailed description of all intervention and comparison conditions that are proposed for the trial and give a rationale for each. Clearly specify the way in which proposed intervention activities are based on findings from the formative research and behavioral theory (include the intervention curriculum in the Appendix;

e. Describe procedures for involving the target population and their advocates or service providers in the design of research and intervention activities;

(1) State whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits will be documented.

(2) Describe the proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation.

f. Describe procedures for obtaining informed consent and maintaining participant confidentiality and;

g. Describe plans to develop specific documents necessary to replicate the intervention and to disseminate study findings to community and scientific audiences.

4. Research and Intervention Capability

a. Describe the research team and organizational setting;

b. Describe the professional training and relevant research experience of all staff;

c. Include in the appendix, memoranda of agreement that clearly and specifically document activities to be performed by any external experts, consultants, or collaborating agencies under the cooperative agreement.

5. Staffing, Facilities, And Time Line

a. Explain the proposed staffing, percentage of time each staff member commits to this and other projects, and division of duties and responsibilities for the project;

b. Describe support activities such as project oversight or data management that will contribute to the completion of all research activities;

c. Describe existing facilities, equipment, computer software, and data processing capacity;

d. Describe the procedures to ensure the security of research data and;

e. Provide a time line for the completion of the proposed research.

6. Budget

Provide a detailed, line-item budget for the project and a budget narrative that justifies each line-item.

F. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit.

On or before August 24, 1998, submit the application to: Julia Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98097, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE, M/S E15, Atlanta, Georgia 30305–2209.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Ability To Recruit HIV-Seropositive Men Who Have Sex With Men (20 points)

a. Quality and diversity of methods used to recruit community-based sample(s) of HIV-seropositive men who have sex with men;

b. Ability of applicant to provide data regarding the relative effectiveness of various strategies to recruit community-based samples of HIV-seropositive men who have sex with men;

c. Documented ability to recruit a research sample of HIV-seropositive men who have sex with men in which the majority of participants are men of color.

2. Familiarity With And Access to HIV-Seropositive Men (35 points)

a. Quality of the description of methods used to collect qualitative and quantitative data during formative research phase, including the documented ability to recruit adequate numbers of study participants;

b. Extent to which findings from the applicant's formative research demonstrates an in-depth understanding of the formative data regarding the HIV transmission risk, factors influencing risk taking behaviors, as well as the intervention and service needs of the proposed study population;

c. Extent to which the applicant has disseminated formative research findings regarding HIV-seropositive men who have sex with men to appropriate scientific and community audiences;

d. Quality and depth of the strategies used to involve and solicit input from a diverse group of HIV-seropositive men, their advocates, or service providers.

3. Intervention Research Plan (30 points)

a. Appropriateness of the proposed research hypotheses and intervention outcome measures;

b. Suitability of the proposed intervention subgroups and documented ability to recruit sufficient numbers of men who have sex with men from the proposed study population;

c. Quality and scientific rigor of the research design and methods that will be employed in the intervention trial;

d. Quality of the rationale and curricula for the intervention and comparison conditions, including the extent to which the proposed intervention activities are based on findings from the formative research and behavioral theory;

e. Extent to which the target population, their advocates, or service providers will be involved in the design of research and intervention activities;

f. Adequacy of procedures for obtaining informed consent and maintaining participant confidentiality and;

g. Quality of plans to develop appropriate materials for intervention replication and to disseminate study findings to community and scientific audiences.

4. Research and Intervention Capability (5 points)

a. Applicant's ability to carry out the proposed research as demonstrated by the training and experience of the proposed research team and organizational setting;

b. Ability of the applicant to conduct the proposed research as reflected in the training, research, and behavioral intervention experience of staff members and;

c. Extent to which services to be provided by external experts, consultants, or collaborating agencies are documented by memoranda of agreement in the appendix.

5. Staffing, Facilities, And Time Line (5 points)

a. Availability of qualified and experienced personnel with sufficient time dedicated to the proposed project. Presence of behavioral scientists in key leadership positions on the project;

b. Clarity of the described duties and responsibilities of project personnel;

c. Adequacy of the facilities, equipment, data management resources, and systems for ensuring data security and;

d. Specificity and reasonableness of time line.

6. The Degree to Which the Applicant Has Met the CDC Policy Requirements Regarding the Inclusion of Ethnic and Racial Groups in the Proposed Research (5 points)

This includes:

a. The proposed plan for the inclusion of 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.

7. Does the Application Adequately Address the Requirements of Title 45 CFR Part 46 For The Protection of Human Subjects?

____ YES ____ No

Comments: _____

8. Budget (not scored)

Extent to which the budget is reasonable, itemized, clearly justified, and consistent with the intended use of funds.

H. Other Requirements

1. Technical Reporting Requirements

Provide CDC with original plus two copies of

a. Semi-annual progress reports, no more than 30 days after the end of each reporting period. The progress reports must include the following for each program, function, or activity involved:

(1) A comparison of accomplishments of the goals established for the period;

(2) Reasons that any goals were not met and;

(3) A description of steps taken to overcome barriers to the goals for the period.

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

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Julia Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE, M/S E–15, Atlanta, GA 30305–2209.

4. The following additional requirements are applicable to this program. For a complete description of each, see Attachments.

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Racial and Ethnic Minorities in Research
AR98–4 HIV/AIDS Confidentiality Provisions
AR98–5 HIV Program Review Panel Requirements
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Section 301 and 317(k)(2), of the Public Health Service Act (42 U.S.C. 241 and 247b(k)(2)) as amended. The Catalog of Federal Domestic Assistance number is 93.941.

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.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Julia Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE, Room 300, Mailstop E–15, Atlanta, GA 30305, telephone: (404) 842–6871; Email *JXV1@CDC.GOV*.

Programmatic technical assistance may be obtained from: Robert Kohmescher Division of HIV/AIDS Prevention, National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E–44, Atlanta, GA 30333, telephone (404) 639–8302 Email *RNK1@CDC.GOV*.

This announcement will be available on CDC's home page at http://www.cdc.gov.

John L. Williams,

Director, Procurement and Grants Office.

[FR Doc. 98–18200 Filed 7–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 98081]

Notice of Availability of Fiscal Year 1998 Funds National Diabetes Prevention Center

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for a National Diabetes Prevention Center whose functions will be to provide guidance and technical support regarding diabetes mellitus (DM) in Native American communities throughout the United States. Initial activities will target the challenges of DM in the Navajo Nation and the Zuni Pueblo tribe in the southwestern United States. If, and as additional funds become available, it is CDC's intent to expand this program to other Native American populations through collaboration with other federal agencies, such as, Indian Health Service (IHS). This program addresses the ''Healthy People 2000'' priority area(s) of Diabetes and Chronic Disabling Conditions. Native American populations have a high incidence and prevalence of diabetes and diabetes complications. The purpose of this initiative is to establish a National Diabetes Prevention Center in Gallup, New Mexico, that will serve as a focal point for developing and testing new prevention and control strategies to address the burden of diabetes in Native Americans. Components of the center will include, but are not limited to, systematic community needs assessment, design, and development of coherent, theory-based community programs, implementation of community interventions, and focused interventional research, surveillance, program evaluation, health professional and community training, and tribal capacity building activities for diabetes prevention and control. The goal is to develop, evaluate and disseminate culturally relevant community based public health prevention strategies for Native Americans. It is envisioned that documented experiences, qualitative, and quantitative research findings, strategies, and benefits from all center activities including initial targeted programs, will ultimately be applicable to other Indian tribes and similar populations. All these activities will require established experiences in qualitative and quantitative assessment, creative theory-based program development, systematic program evaluation, and management and supervisory activities. Cooperative partnerships will be important in center activities.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, including State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations may apply.

Congress, through the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, H.R. 2264, 1998 Conference Report, page S–12088 directed CDC to establish a National Diabetes Prevention Center in Gallup, New Mexico, with initial activities involving and targeting the Navajo Nation and Zuni Pueblo tribe in the southwest U.S.

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 $2.3 million is available in FY 1998 to fund this program. It is expected that this one award will begin on or about September 30, 1998, and will be made for a 12-month budget period within a project period of up to five 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.

Direct Assistance

Applicants may request Federal personnel, equipment, or supplies as direct assistance, in lieu of a portion of financial assistance.