DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02136]

Reducing Sexual Risk for HIV Transmission in Substance-Using Men Who Have Sex With Men; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program to support research on interventions to reduce sexual risk for HIV transmission in substance-using men who have sex with men (MSM). This program addresses the ''Healthy People 2010'' focus HIV.

The purpose of the research is to develop and test behavioral interventions that focus on reducing risk for HIV transmission by altering the sexual risk behavior of substance using and abusing MSM. Under this program, the primary outcome of the project will be the development of effective interventions for substance-using MSM which may then be adapted and replicated by community-based HIV prevention and substance abuse agencies among sub-populations of substance-using MSM throughout the U.S. This announcement addresses goals of CDC's HIV Prevention Strategic Plan.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for HIV, STD & TB Prevention. Through the implementation of HIV prevention programs, reduce the number of cases of HIV infection and AIDS: 1. acquired heterosexually, 2. related to injecting drug use, 3. associated with male-to-male homosexual contact, and 4. acquired perinatally.

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, faith-based organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: *Title 2 of United States Code 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 or loan.

C. Availability of Funds

Approximately $1,200,000 is expected to be available in FY 2002 to fund up to four awards for the first year of project activities. It is expected that the average award will be approximately $300,000 in the first year to support development of an intervention in additional years and will begin on or before September 30, 2002. The award will be made for a 12-month budget period, within a project period of up to five years. Funding estimates are expected to increase once recruitment and intervention activities begin. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports, satisfactory participant accrual, and the availability of funds. The Catalog of Federal Domestic Assistance number is 93.943.

Funding Preference

Funding decisions will attempt to achieve regional diversity of the four sites (e.g., Northeast, South, Central, West). Funding decisions will also take into consideration geographical locations that afford sufficient numbers of men from which to sample.

D. Program Requirements

In conducting activities to achieve the purpose of these programs, the recipient will be responsible for the activities listed under Recipient Activities, and CDC will be responsible for conducting activities listed under CDC Activities:

1. Recipient Activities

The program will support four sites to work collaboratively with each other and with Federal investigators in conducting an intervention study to reduce sexual risk-taking among substance abusing MSM. At each site, it is expected that grantees will newly enroll a minimum of 375 men, including non-injection drug and other substance-using (including alcohol) gay identified and non-gay identified MSM.

The interventions to be tested should be theory-based, group-level interventions appropriate for use among a culturally-diverse population of MSM who reside within a challenging socio-cultural context. Intervention strategies should be sufficiently brief and of a technical level that would facilitate rapid dissemination among community-based organizations. Approximately one-third of the men should identify as African American, one-third as Hispanic/Latino and one-third as Caucasian at each study site. Men who are recruited into the study must currently use drugs and/or alcohol at a heavy level and have been sexually active within the past three months. Men recruited into the study can be poly-drug users (including alcohol), but without current intravenous drug use. Men can be recruited from a variety of venues, including drug using venues, bars, public sex environments known also to be sites for drug/alcohol use as well as substance abuse treatment organizations. The design of the study should include an attention control strategy, so that men randomized to the control condition are invited to equivalent time spent in groups that focus on an issue of interest to this population.

Applicants should develop (1) sampling and recruitment strategies that ensure that the study includes a demographically diverse group of MSM, (2) culturally-sensitive measures of antecedent and outcome variables, including both quantitative and qualitative assessments, (3) an intervention plan that relates directly to an identified theoretical model of sexual risk reduction, (4) a core set of measures that will facilitate assessment of substance use and sexual risk behavior, (5) a sampling plan that will successfully recruit and retain a large number of research participants whose substance use is associated with high risk sexual behavior at some level, and (6) stringent safeguards for protecting confidentiality of participants.

Applicants must develop protocols and assessment instruments that will increase understanding of a broad array of sociocultural, structural, psychological, and behavioral factors as they relate to HIV infection risk in substance-using MSM. These factors must be addressed in the design of intervention activities, so that the forces that are promoting high risk sexual activity within these populations are addressed in the intervention. Clear hypotheses should be developed to test how these variables—and drug and alcohol use themselves—mediate or moderate target risk behaviors. After sites are funded, but before research activities begin, grantees and Federal investigators will work collaboratively to refine the protocols so that they fit together across sites and address

behavioral intervention research issues in a scientifically rigorous manner.

Collaborate with other Federally sponsored researchers, including developing and using common data collection instruments and data management procedures, as determined in post-award grantee planning conferences.

Recipients will be required to pool data for analysis and publication, but can also conduct independent site-specific analyses, as agreed to by the multi-site study group. Recipients are also required to work collaboratively as a study group to:

a. Attend meeting(s) at CDC to develop collaborative research protocol.

b. Develop the research study protocols and standardized data collection forms across sites, including standardized measures of drug and alcohol use and high risk sexual behaviors.

c. Prepare an IRB protocol for approval at the local and CDC levels.

d. Identify, recruit, obtain informed consent from, and newly enroll an adequate number of study participants as determined by the study protocols and the program requirements.

e. Follow study participants as determined by the study protocols.

f. Develop the intervention and intervention procedures in collaboration with the other funded investigators and implement the intervention as defined in study protocols.

g. Establish procedures to maintain the rights and confidentiality of all study participants.

h. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocols.

i. Collaborate and share data (when appropriate) with other collaborators to answer specific research questions.

j. Conduct data analysis with all collaborators.

k. Present and publish research findings.

l. Participate in conference calls with all collaborators.

m. Attend scheduled meetings with other funded grantees.

2. CDC Activities

a. Provide technical assistance as needed in intervention development and in the design and conduct of research.

b. 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.

c. Assist as needed in designing a data management system.

d. Assist as needed in performance of selected laboratory tests.

e. Work collaboratively with investigators to help facilitate research activities across sites involved in the same research project.

f. Analyze data and present findings at meetings and in publications.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop your application. Your application will be scored based on the criteria listed in the Evaluation Criteria, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 double-spaced pages, printed on one side with one inch margins in a 12-point font or greater. Follow the directions for completing the application that are found in the Public Health Service (PHS) 398 kit.

F. Submission and Deadline

Submit the original and two 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 and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm.*

On or before July 31, 2002 submit the application to:

Technical Information Management Section, PA #02136, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146.

Deadline: Applications shall be considered as meeting the deadline if they are:

Received on or before the deadline date.

Late Applications: Applications which do not meet the criteria above will be returned to the applicant.

G. Evaluation Criteria

Application

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of Effectiveness must relate to the performance goal (or goals) as stated in section ''A. Purpose'' of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC. Applications will be ranked on a scale of 100 maximum points. Applications will be reviewed and evaluated based on the evidence submitted and the applicant's abilities to meet the following criteria:

1. Familiarity With and Access to the Study Population (25 points)

a. Extent of the applicant's knowledge of issues faced by study population, including substance use and sexual risk behaviors, access to the study population and experience in working with the population.

b. Existence of linkages to facilitate recruitment from and referral to community-based programs providing services for the study population, including letters of support given in an appendix.

c. Feasibility of plans to involve the study population, their advocates, or service providers in the development of research activities and to inform them of research results.

d. Feasibility of plans for recruitment and outreach to new study participants (e.g. not men currently enrolled in an ongoing study).

2. Description and Justification of an Intervention and Research Plan (40 points)

a. Quality of the review of the scientific literature pertinent to the proposed study, including the theoretical basis for the investigation and relevance of research questions.

b. The originality of the research, including the extent to which it addresses important gaps in knowledge and has strong relevance for guiding behavioral interventions.

c. Applicant's understanding of the research objectives as evidenced by the quality of the proposed research plan, specific study design and the choice of the theory to guide the intervention activities as well as the quality of the plan to operationalize intervention activities.

d. Feasibility of plan to sample, recruit, obtain informed consent and newly enroll 375 study participants in a culturally and linguistically appropriate manner. This includes plans for achieving a demographically diverse sample within the African-American and Hispanic populations, conducting multi-venue sampling.

e. Feasibility of plan for collecting both quantitative and qualitative formative research data and to follow research participants over time.

f. Comprehensiveness of the plan to protect the rights and confidentiality of all participants.

g. Thoroughness of statistical analysis plans, including data cleaning, management, and substantive analyses, and plans for timely provision of data for pooled analyses.

h. Extent to which study proposal demonstrates agreement to comply with multi-site research requirements (e.g., common protocol, data collection, and computer and data management systems).

i. The degree to which the applicant has met the HHS Policy requirements regarding the inclusion of ethnic and racial groups in the proposed research. This includes: (1) the proposed plan for the inclusion of 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;

j. Provide 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.

k. Provide general time line for conducting the research and a detailed time line for the first year of the study, including measurable process objectives for the first year of the study.

3. Demonstration of Staff's Capability to Conduct Research (20 points)

a. Applicant's ability to carry out the proposed research as demonstrated by the training, experience, and expertise of the principal investigator and the proposed research team and organizational setting, including demonstration of ability to collect, manage, and analyze accurate data in a timely manner.

b. Evidence of plan for establishing a partnership with at least one community based organization to link participants with prevention and medical services as needed, and to consult on study procedures as needed.

c. Demonstration of epidemiologic, behavioral intervention, clinical, administrative, and management expertise needed to conduct the proposed research.

d. Demonstration that principal investigator and staff have experience working with the targeted population of study participants.

e. Demonstration that investigative team includes a staff member with expertise in qualitative formative data analysis.

4. Staffing, Facilities, and Time-Line (15 points)

a. Availability of qualified personnel with realistic and sufficient percentage-time commitments (including an estimated staffing plan for years in which intervention activities will occur); clarity of the described duties and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, epidemiologic, clinical, administrative, data management, and statistical aspects of the research.

b. Adequacy of the facilities, equipment, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

c. Adequacy of base staff to keep pace with anticipated workload.

d. Adequacy of time-line for conducting the research.

5. Other (not scored)

a. Budget: The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: The application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. annual progress reports;

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 section J (''Where to Obtain Additional Information'') of this document.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–4 HIV/AIDS Confidentiality Provisions
AR–5 HIV Program Review Panel Requirements
AR–6 Patient Care
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317 (k)(2)of the Public Health Service Act, [42 U.S.C. section 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.943.

J. 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 ''Funding'' then ''Grants and Cooperative Agreements.''

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Lynn Mercer, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Announcement #02136, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd. Room 3000, Mailstop E–15, Atlanta, GA 30341, Telephone: (770) 488–2810, E-mail address: *lzm2@cdc.gov*.

For program technical assistance, contact: Craig Studer, Deputy Chief, Behavioral Intervention Research Branch, Division of HIV/AIDS Prevention—IRS, National Center for HIV, STD, TB Prevention ,Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–37, Atlanta, Georgia 30333, Telephone: (404) 639–1900, E-mail address: *CStuder@cdc.gov*.

Dated: May 20, 2002.

Edward J. Schultz,

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

[FR Doc. 02–13075 Filed 5–23–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee Meeting: Cancelled.

NAME: Mine Safety and Health Research Advisory Committee (MSHRAC) Meeting—Cancelled.

TIME AND DATE: 11 a.m.–2 p.m., May 22, 2002.