

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) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Atlanta, Georgia, will be the host of the 1996 Summer Olympics Games (July 19 through August 4, 1996). As a result of this event, it is likely that the Procurement and Grants Office (PGO) may experience delays in the receipt of both regular and overnight mail deliveries. Contacting PGO employees during this time frame may also be hindered due to the possible telephone disruptions.

To the extent authorized, please consider the use of voice mail, e-mail, and fax transmissions to the maximum extent practicable. Please do not fax lengthy documents, contract proposals or grant applications.

Dated: June 4, 1996.

Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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#### [Announcement Number 638]

### **Development and Feasibility Testing of Interventions to Increase Health-Seeking Behaviors in, and Health Care for, Populations at High Risk for Gonorrhea**

#### **Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program to conduct research to: (a) Identify factors (at the client, provider, and systems levels) that influence the health-seeking behaviors of, and health services for, populations at high risk of transmitting and acquiring gonorrhea; (b) use the above information to develop and test interventions to increase health care seeking and improve health care; and (c) develop interdisciplinary approaches and augment a behavioral research infrastructure related to sexually transmitted diseases (STDs).

CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000", a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority

areas of STDs and HIV Infection. (For ordering a copy of "Healthy People 2000," see the section "WHERE TO OBTAIN ADDITIONAL INFORMATION.")

#### **Authority**

This program is authorized under section 318 of the Public Health Act [42 U.S.C. 247c], as amended.

#### **Smoke-Free Workplace**

The CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

#### **Eligible Applicants**

Applications may be submitted by public and private, nonprofit and for-profit research organizations and their agencies. Thus, universities, colleges, hospitals, research institutions and other public and private organizations and small, minority and/or women-owned businesses are eligible to apply. Also, organizations described in section 501 (c)(4) of the Internal Revenue Code of 1986 that engage in lobbying are not eligible to receive Federal grant/cooperative agreement funds.

#### **Availability of Funds**

Approximately \$1 million is available in FY 1996 to fund approximately 5 awards. The project will be conducted in two stages. The project period for Stage I is expected to be two years. For Stage I, it is expected that the average award will be \$250,000, ranging from \$200,000 to \$300,000. It is expected that the awards will begin on or about September 30, 1996, and will be made for a 12-month budget period. Funding estimates may vary and are subject to change. Before completion of Stage I, recipients will compete for continuation awards for Stage II which is expected to be an additional two years. Successful completion of Stage I is required to compete for Stage II.

#### **Stage I—(Years 1 & 2)**

Focuses on formative research to identify client, provider, and system level determinants of health care seeking by, and health care for, populations at high risk of transmitting and acquiring gonorrhea.

#### **Stage II—(Years 3 & 4)**

Focuses on developing and testing the client, provider, and system level

interventions to increase health care seeking by, and to improve health care for, populations at risk for gonorrhea.

Further detail on Stages I and II is presented below under the "PURPOSE" section. Continuation awards within an approved project period will be based on satisfactory progress and the availability of funds.

#### **Purpose**

The overall purpose of this program is to assist the recipients in developing and utilizing behavioral and social science research methods to learn the influences on health care seeking and health care at the client, provider, and system levels, and to use this information to develop:

- \* Community-level behavioral interventions to increase health care seeking and;

- \* Provider and systems interventions to improve health care for populations at high risk of transmitting and acquiring gonorrhea.

The research program has two stages of activity and funding:

*Stage I: Formative Research and Intervention Development.*

*Stage II: Intervention Implementation and Feasibility Testing.*

The fundamental goal of this program announcement is best understood in the context of Stage II (years 3 and 4 of the anticipated 4-year project), in which the grantees will implement and evaluate the feasibility of a science-based community intervention to increase health care seeking among those at high risk for gonorrhea. In addition, the recipients will implement and evaluate the feasibility of science-based provider and systems interventions to improve health care for this same population. Applications for such Stage II intervention activities are not required at this time because well-developed, science-based, promising approaches to changing health-seeking behavior or the provision of health care will be based upon the aggregate results of the research conducted by grantees during Stage I.

#### **Program Requirements**

The following are applicant requirements:

(1) For research institutions, a documented research partnership with a public health agency of a State or local government or their bona fide agents. For health agencies, a documented research partnership with a university or other qualified research institution. Applicants are also encouraged to demonstrate ongoing collaboration with community-based organizations (CBOs)

that have histories of access to and success with the target population;

(2) Proof that the catchment area has  
(a) A calendar year (CY) 1995 gonorrhea incidence rate that is higher than 225 per 100,000 or 750 per 100,000 for 15 to 19 year olds, and

(b) Access to at least 500 new cases of gonorrhea per year;

(3) Include documentation of a multi-disciplinary research team with behavioral, clinical, epidemiologic, and health economics or health services research expertise, as well as in statistics or data management;

(4) State a willingness to participate in the development and implementation of common protocols and methods for formative research on client, provider, and system determinants of health care seeking by, and health care provision to, populations at high risk of transmitting and acquiring gonorrhea.

Applications that do not satisfy these eligibility requirements will not be considered and will be returned.

#### Cooperative Activities

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities under B. (CDC Activities), as listed below:

##### A. Recipient Activities

1. Develop an overall framework that would allow gonorrhea research to be conducted that would validate, verify, and expand upon the initial choice of a catchment area and target population. Specify the demographics of the target population and any subgroups.

2. Develop an intervention and justify the selection of a particular subgroup toward which to direct future interventions.

3. Verify access sites within the catchment area (e.g., STD clinics, school-based clinics, job training sites, health centers, substance abuse treatment facilities; shelters or drop-in facilities for runaway and homeless youth, mental health clinics, other health care facilities such as community health centers, facilities "without walls" that provide outreach to "hard-to-reach" populations; units within the criminal justice system) where populations at risk for gonorrhea will potentially be accessible for interviewing and for the intervention.

4. Conduct qualitative and quantitative behavioral and psychosocial research to identify client, provider, and system factors influencing health care seeking by, and health care for, populations in the catchment areas

at risk of acquiring and transmitting gonorrhea.

5. Develop common protocols to conduct this formative research. In particular, CDC and the recipient will agree on appropriate sampling approaches for the collection of behavioral and psychosocial data. Recipients may enhance the common protocol or develop additional protocols to address questions and issues specific to their local conditions.

6. Develop assessment instruments and participate in cross-site implementation of those instruments. Each recipient will analyze and report results of this three-level assessment and will produce a report synthesizing knowledge about the community. This report should reflect the community's health care system in the current era of health care reform, with particular attention to the type of health care coverage extended to subgroups in the community and the number of persons enrolled in these plans.

7. Manage, analyze, and interpret data. Data from the Stage I activities must be collected, managed, and stored securely and confidentially. Recipients will use common computer and data management systems and will have submitted the data from their client, provider, and system assessments in appropriate format to CDC.

Any materials developed in whole or in part with CDC funds shall be subject to a nonexclusive, irrevocable, royalty-free license to the government to reproduce, translate, publish, or otherwise use and authorize others to use for government purposes.

8. Travel to Atlanta or another location and participate with other recipients and CDC representatives in four meetings during Stage I. The first meeting will be held within 60 days after awards are made to develop common approaches and instruments for the Stage I formative research.

9. Assemble a local Internal Review Board (IRB) for each catchment area to review protocols developed under this program and submit approvals to CDC.

10. Provide progress reports to representatives of communities affected by gonorrhea and other involved organizations, agencies, and persons.

By the end of Stage I (24 months), it is expected that each recipient will have:

1. Completed formative research, data reduction, and will have prepared research summaries and a final report. This report should, at a minimum, identify client, provider, and system determinants of health care seeking and health care provision behaviors.

2. Established access to the target population in sufficient numbers to provide meaningful sample sizes for feasibility studies of community interventions as a condition of going on to Stage II feasibility research.

3. Established access to providers or health care systems in order to carry out provider and system interventions as a condition of going on to Stage II research.

4. Demonstrated that their proposed catchment areas are minimally affected by confounding factors or have identified appropriate methods for controlling competing interventions and research.

##### B. CDC Activities

1. Provide scientific and technical oversight in the general operation of the formative stage of the gonorrhea prevention and health care behavior project.

2. Host a meeting of the recipients to plan common approaches and protocols for the formative research stage (years 1 and 2) of this initiative. CDC will host three other meetings of recipients during Stage I to promote collaboration.

3. Monitor and evaluate scientific and operational accomplishments of this project through periodic site visits, frequent telephone calls, and review of technical reports and interim data analyses.

4. Assist recipients in the aggregation of data and analysis and distribution of results of multisite analyses.

##### Evaluation Criteria

Applications that meet the eligibility requirements will be reviewed and evaluated according to the following criteria:

1. Understanding of the objectives of this research as reflected in the statement of research background and research questions. (15 points)

2. Documentation of the epidemiologic, demographic, and health care and prevention program characteristics of geographical catchment area in which the applicant will have access to at least 500 cases of new gonorrhea per year. (15 points)

3. Appropriateness of the methodologies initially proposed for formative research on client, provider, and system determinants of health care seeking by and health care for populations at high risk of transmitting and acquiring gonorrhea. (20 points)

4. Overall ability (that of the applicant and proposed sites) to perform the technical aspects of the project as reflected in the availability of qualified and experienced personnel for a multi-disciplinary team; facilities and plans

for the administration of the project, including a detailed and realistic schedule for the specified activities and access to study populations, providers, and health care institutions. (20 points)

5. The extent to which the research approach is interdisciplinary and culturally and programmatically relevant. (5 points)

6. 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 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; and

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

7. The extent to which collaborations among health departments, research institutions, and other participating health care entities are likely to be sustained for the duration of the project. (5 points)

8. Documentation of experience with behavioral interventions for bacterial STDs. (5 points)

9. Consideration of the extent to which the formative research activities conducted in Stage I will result in Stage II pilot intervention protocols for testing the feasibility of client, provider, and system interventions. (10 points)

10. In addition, consideration will be given to the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds. (Not scored)

#### Funding Preferences

Final determination may be influenced by the geographic distribution of project sites. In addition, due to the changes in the health care system, consideration will be given to funding at least one applicant who has contractual research agreements with a managed care organization.

#### Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance

applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. A current list of SPOCs is included in the application kit. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-15, Atlanta, GA 30305, no later than 60 days after the application deadline. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" State process recommendations it received after that date.

#### Public Health System Reporting Requirement

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernment applicants must prepare and submit the items identified below to the head of the appropriate State or local health agency in the program areas(s) that may be affected by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF424); and

B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not to exceed one page, and include the following:

1. A description of the population to be served;

2. A summary of the services to be provided; and

3. A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health officials should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.978.

#### Other Requirements

##### *Paperwork Reduction Act*

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

##### *Confidentiality*

Applicants must have in place systems to ensure the confidentiality of patient records.

##### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

##### *Women, Racial and Ethnic Minorities*

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting review for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and scoring.

This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of the subjects. Further guidance to this

policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, dated Friday, September 15, 1995.

#### Application Submission and Deadline

##### A. *Preapplication Letters of Intent*

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. On or before July 5, 1996, the letter should be submitted to Kimberly P. Boyd, 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, Atlanta GA 30305. The letter should identify the announcement number and the name of the investigator. The letter does not influence review or funding decisions, but will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

##### B. *Applications*

The original and two copies of the application PHS 5161-1 (OMB Number 0937-0189) must be submitted on or before August 5, 1996, to Mr. Van Malone, Grants Management Officer, Attention: Kimberly Boyd, 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 E15, Atlanta, GA 30305.

##### C. *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 in time for submission to the objective review group.

(Applicants must request a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailing.)

(c) Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

#### 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 Kimberly Boyd, 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 E15, Atlanta GA 30305, telephone (404) 842-6592, Facsimile (404) 842-6513, or Internet at <KPT0@OPSPGO1.em.cdc.gov>. Programmatic technical assistance may be obtained from Sevgi Aral, Ph.D., Division of STD Prevention, Behavioral Interventions and Research Branch (BIRB), National Center for STD, HIV, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E02, Atlanta, GA 30333, telephone (404) 639-8259, Facsimile (404) 639-8608.

Please refer to Announcement Number 638 "Development and Feasibility Testing of Interventions to Increase Health-Seeking Behaviors in, and Health Care for, Populations at High Risk for Gonorrhea" when requesting information and submitting an application.

You 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) referenced in the "INTRODUCTION" from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

There may be delays in mail delivery and difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics. Therefore, CDC suggest applicants use Internet, follow all instructions in this announcement and leave messages on the contact person's voice mail for more timely responses to any questions.

Dated: June 4, 1996.

Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

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#### [Announcement 627]

### Replication of Effective HIV Behavioral Interventions

#### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program for replicating HIV behavioral interventions which have been found to

be effective in intervention research studies. This announcement supports the development and implementation of plans, materials, and training to accomplish the replication of the intervention in one site.

The CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area Human Immunodeficiency Virus (HIV) Infection. (For ordering a copy of "Healthy People 2000," see the section "WHERE TO OBTAIN ADDITIONAL INFORMATION.")

#### Authority

This program is authorized under sections 301 and 317(k), of the Public Health Service Act [42 U.S.C. 241 and 247b], as amended.

#### Smoke-Free Workplace

CDC strongly encourages all recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

#### Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutes, hospitals, other public and private organizations, State and local health departments or their bona fide agents or instrumentalities, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women- owned businesses are eligible to apply.

Note: Organizations described in section 501(c)(4) of the Internal Revenue Code of 1986 that engage in lobbying are not eligible to receive Federal grant/cooperative agreement funds.

#### Availability of Funds

Approximately \$900,000 is available in FY 1996 to fund approximately 5 awards. It is expected that the average award will be \$200,000, ranging from \$175,000 to \$225,000. It is expected that the awards will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of 2 years. Funding estimates may vary and are subject to change based on availability of funds.