

Attendance at this workshop is not mandatory. Applicants who are currently funded by CDC may not use project funds to attend this workshop.

Each potential applicant may send no more than two representatives to this meeting. Please provide the names of the persons that are planning to attend this meeting to Elizabeth Majestic, Chief, Special Populations Section, Division of Adolescent and School Health; telephone (404) 488-5356; no later than July 2, 1996.

Dated: June 11, 1996.

Joseph R. Carter,

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

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[Announcement 628]

Outcome Evaluations of HIV/AIDS Prevention Interventions

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 outcome evaluations of existing innovative interventions designed to reduce the transmission of the human immunodeficiency virus (HIV).

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 of 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)(2), of the Public Health Service Act (42 U.S.C. 241 and 247b(k)(2)) 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 \$500,000 is available in FY 1996 to fund approximately three awards each evaluating a different intervention strategy in a different high-risk population. It is expected that the average award will be \$150,000, ranging from \$125,000 to \$175,000. Awards are expected to begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Definitions

For the purposes of this program, an Innovative HIV Prevention Intervention is an HIV prevention strategy that has not been extensively researched in the context in which it is being applied or one that represents a new approach to the integration of known prevention strategies. The terms Outcome Evaluation and Effectiveness Study are used somewhat interchangeably and refer to the design and methods used to assess the short- or long-term effects that can be reasonably attributed to the intervention.

The term HIV Community Planning Priorities are priorities based upon the epidemiologic profile of HIV in a community as determined by the Community Planning Group (CPG). For example, if a CPG determined that there is a significant problem of HIV intravenous drug (ID) use in the community then the funding of HIV prevention strategy for ID use would be a priority for HIV community planning.

Purpose

The purpose of this program is to support intervention effectiveness

studies that assess social, behavioral, programmatic, and policy outcomes of specific innovative HIV prevention interventions. These outcome evaluations should assess prevention interventions that are innovative, have new components or involve the innovative application of interventions that are commonly employed (e.g. HIV counseling and testing) and have potentially broad relevance to the field of HIV prevention. These evaluation studies will use methods common to rigorous outcome evaluation research (e.g. comparison groups, individual baseline data, cohorts, cross-sectional surveys) within the limits of the funding available and appropriately matched to the nature and size of the intervention.

This program is designed to provide evaluation resources to organizations that might not otherwise have the resources to determine the effectiveness of their programs. Funds are intended solely to implement the evaluation and not to support the intervention itself. Interventions being evaluated should target high-risk populations (e.g. men who have sex with men, injection drug users and their partners, youth in high risk situations).

Lastly, this program is to devise practical, yet reasonably rigorous, outcome evaluation methods and designs that integrate both qualitative and quantitative data, possibly from multiple sources, in the analysis and interpretation of the findings.

Program Requirements

The application should demonstrate the applicant's ability to design and implement the evaluation, analyze the data, and disseminate the findings. 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 listed under B. (CDC Activities).

A. Recipient Activities

Recipients will be asked to attend meetings in Atlanta approximately twice a year to brief CDC staff on the project and discuss key decisions. Additionally the recipient should expect to host periodic (up to 4 per year) site visits by the CDC project officer.

1. Prepare a detailed evaluation protocol, including a description of the intervention and how it is innovative, the study research questions, proposed methods, including sampling, assessment, and analysis plans, draft measurement instruments, and project timelines.

2. Develop measures to evaluate the intervention. New instruments should be field-tested.

3. Develop procedures to ensure confidentiality and informed consent when appropriate and obtain IRB clearances as needed.

4. Recruit study subjects and comparison groups according to the evaluation design.

5. Conduct individual baseline and repeat assessments according to the evaluation design.

6. Establish data management systems, analyze and interpret the data.

7. Prepare a final report for CDC, including submission of a cleaned data set.

8. Prepare a paper that summarizes the results and recommends future research and describes programmatic implications.

9. Present the findings locally. Collaborate with other recipients in presenting the findings at national meetings.

B. CDC Activities

1. Assist the recipient in planning and implementing the evaluation, including providing technical guidance in the development of the study design, data collection instruments, selection of comparison groups, outcome measures, data collection protocols, and pretesting of methods and instruments.

2. Provide project oversight and technical assistance.

3. Assist in analyzing the data and interpreting the results.

4. Assist in presenting the findings.

Evaluation Criteria

Before submitting an application, applicants will need to identify an innovative behavioral or social HIV prevention intervention that is designed to reduce risk behaviors by high-risk persons or within high-risk communities. Communities may be defined by geopolitical boundaries or by relational affiliations (e.g., men who have sex with men, African American community, youth in high risk situations).

Evaluation criteria are based upon the responsiveness to, and the quality of, specific information requested in the "Application Content" section of the program announcement included in the application kit.

1. Justification and Significance of the Intervention (30 Points)

The degree to which the intervention is innovative, i.e., new or represents a new approach to the integration of known prevention strategies and has not yet been extensively evaluated in the

context in which it is being applied. The extent to which the intervention has broader significance or relevance for HIV prevention. In determining significance, consideration will be given to the degree to which the selected intervention is based on behavioral or social science theory, public health practice or program experience and the relevant research literature, including a description of the social and contextual issues if relevant. Degree to which clear intervention goals and objectives are articulated. Degree to which the behavioral or social interventions complement other biomedical or socioenvironmental interventions. The degree to which the proposed activity is significant to HIV prevention. The degree to which the intervention is generalizable.

2. Evidence That Target Population Reflects HIV Community Planning Priorities (10 Points)

Degree to which the local, regional or State HIV prevention community plan, especially the epidemiologic profile and behavioral data, were used in the selection of the intervention. The degree to which the target population is described clearly and concisely. Evidence that the intervention has access to sufficient numbers of the target population to show intervention effects is also important.

3. Soundness of the Evaluation Plan (30 Points)

The extent to which the evaluation plan, including the stated research or evaluation question, study design and methods, comparison groups, data collection instruments and plans for analysis, are scientifically sound and capable of producing the intended results. The degree to which the plan is clear, complete, and includes time-related milestones that CDC and recipients can use to gauge progress. The degree to which plans for data management, analysis, and interpretation are appropriate and reflect the intention to collaborate with CDC. Reasonableness of plans for collecting and integrating qualitative and quantitative data from multiple sources.

4. Adequacy of the Dissemination Plan (10 Points)

Degree to which a dissemination plan is articulated. Evidence that the applicant is committed to disseminating findings locally and collaborating with CDC in disseminating findings nationally. The degree to which the applicant is committed to collaborating with CDC in coauthoring papers.

5. Evidence of Collaboration and Capacity To Undertake the Evaluation (20 Points)

Quality of supporting evidence (letters and memorandums of agreement) that the applicant has the full support of all specified collaborators. The degree to which the applicant has the scientific and programmatic capacity and proven track record in successfully designing, implementing and completing similar evaluations, either alone or in partnership with the proposed collaborator. The degree to which the affected population seems to be involved in planning the evaluation. (To obtain specific information on the community plan for your location, please contact your local health department.)

In addition, the degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

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

b. The appropriateness of the proposed justification when representation is limited or absent.

c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

6. Budget (Not Scored)

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

Funding Preferences

All applicants are encouraged to provide evidence of support from their local health departments. Preference will be given to applicants who collaborate with representatives of target populations at highest risk for HIV infection and who are served by the program being evaluated. Special consideration will be given to applications to evaluate innovative interventions to integrate or link multiple intervention components, for example, provision of HIV counseling and testing services by nongovernmental organizations (NGOs) that serve high-risk communities and also provide innovative behavior-change services.

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 (other than federally recognized Indian tribal governments) 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. 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., Room 300, Mailstop E15, Atlanta, GA 30305, no later than 30 days after the application deadline (the appropriation for this financial assistance program was received late in the fiscal year and would not allow for an application receipt date which would accommodate the 60-day State recommendation process period). The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to the CDC, they should forward 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., Room 300, Mailstop E15, Atlanta, GA 30305. This should be done no later than 30 days after the application deadline date. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the

items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted 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 (SF 424).

B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not 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 official should desire a copy of the entire application, it may be obtained from the Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.941.

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.

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. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. 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 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. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of 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

The original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 255 East Paces Ferry Road, NE., Room 300, Mailstop E-15, Atlanta, GA 30305, on or before August 5, 1996.

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

a. Received on or before the deadline; or

b. Sent on or before the deadline date and received in time for submission to the objective review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.a. or 1.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

To receive additional written information call (404) 332-4561. You

will be asked to leave your name, address, and telephone number and will need to refer to Announcement 628. You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Adrienne Brown, 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) 842-6634, email: <asm1@opspgo1.em.cdc.gov>. Programmatic technical assistance be obtained from Deborah L. Rugg, Ph.D., Program Evaluation Branch, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E-59, Atlanta, GA 30333, telephone (404) 639-0952, FAX (404) 639-0923, e-mail: <dlr1@oddhiv1.em.cdc.gov>.

Please refer to Announcement 628 when requesting information and submitting an application.

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.

Internet Home Page

The announcement will be available on one of two Internet sites on the publication date: CDC's home page at <<http://www.cdc.gov>>, or at the Government Printing Office home page (including free access to the Federal Register) at <<http://www.access.gpo.gov>>.

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

Dated: June 11, 1996.

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

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[Announcement Number 639]

Resident Postdoctoral Research Associates Program in Microbiology

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds to provide assistance for developing and conducting a Resident Postdoctoral Research Associates Program in Microbiology.

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 of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where To Obtain Additional Information.)

Authority

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

Smoke-Free Workplace

CDC encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. 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

Assistance will be provided only to public or nonprofit, private scientific organizations. Eligible applicants must be national in scope, devoted to scientific pursuits in all areas of microbiology that relate to infectious diseases, including general, clinical, medical, environmental, animal virology, molecular microbiology, immunology and medical technology, and have experience in administering postdoctoral training programs in medical microbiology and public health microbiology which are designed to assist associates conducting microbiologic research to solve medical and public health problems.

Availability of Funds

Approximately \$800,000 is available in FY1996 to fund one award. It is expected that the award will begin on or about September 30, 1996, and is made for a 12-month budget period within a project period of up to 5 years. Funding

estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Purpose

The purpose of this cooperative agreement is to assist the recipient in developing and conducting a Resident Postdoctoral Research Associates Program in Microbiology. The program emphasizes microbiology related to infectious disease prevention and control. Particular emphasis is given to studies at the molecular level. Areas of investigation may include: viral and rickettsial infections, nosocomial infections, acquired immunodeficiency syndrome, vector-borne infectious diseases, respiratory and food-borne bacterial diseases, sexually transmitted diseases, parasitic diseases, and other diseases or conditions relevant to the disciplines of bacteriology, virology, parasitology, medical entomology, mycology, immunology, and pathology. The recipient must be able to provide support for postdoctoral scientists of unusual ability and promise or proven achievement by giving them an opportunity to conduct applied and operational research on significant public health problems identified with these research interests. Associateships should be for a two year period.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A., below, and CDC shall be responsible for conducting activities under B., below:

A. Recipient Activities

1. Develop and conduct a Resident Postdoctoral Research Associates Program in Microbiology to support development of new approaches, methodologies, and knowledge in infectious disease prevention and control.
2. Identify specific research opportunities from descriptions provided by CDC.
3. Establish program policies/procedures for application and selection (e.g., establish applicant eligibility criteria).
4. Develop announcements/advertisements and an application package describing the program, listing research opportunities, and providing application instructions. Widely distribute the announcements and application package with the objective of soliciting applications from qualified individuals throughout the United