

intended to modify the terms of the proposed consent order in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99089]

Notice of Availability of Funds; Technology Translation and Transfer of Effective HIV Behavioral Interventions; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for the technology translation and transfer of effective HIV prevention behavioral interventions. This program addresses the "Healthy People 2000" priority area for Human Immunodeficiency Virus (HIV) Infection.

HIV/AIDS researchers have developed and tested prevention interventions that aim to reduce sex-related and drug-related risk behaviors. A number of these interventions have credible evidence of effectiveness, defined as reporting positive and significant results on an HIV-relevant behavioral or health outcome. The purposes of this project are to:

- (1) Translate effective HIV prevention interventions whose original research was conducted with methodological rigor, preferably at multiple sites with multiple populations at risk;
- (2) Develop packages of materials in collaboration with health departments, community-based organizations, and/or other prevention providers and consumers, that prevention providers can use to replicate the interventions in non-research field situations; and
- (3) Study the process of technology transfer, using the prevention packages in at least one field setting supported by training, quality assurance, and technical assistance.

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, State and local health departments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations.

Note: Pub. L. 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$350,000 is available in FY 1999 to fund approximately two awards. The average award will be \$175,000 and the range will be \$150,000 to \$200,000. It is expected that the awards will begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may vary and are subject to change based on availability of funds. An application requesting greater than \$200,000 (including indirect costs) will not be considered for review and will be returned to the applicant.

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. Continued funding for year two will be dependent on the completion of required activities for year one.

Use of Funds

Collection of new or supplemental intervention research data, data entry and analysis, purchase of furniture or computers, and rental of facilities will not be funded under this program.

D. Program Requirements

In conducting activities to achieve the purpose of this announcement, the recipient will be responsible for the activities under 1, Recipient Activities, and CDC will be responsible for the activities listed under 2, CDC Activities.

1. Recipient Activities

The program requirements for the first year of activity are:

- a. Develop the (1) intervention portion of the prevention package and (2) preliminary versions of the training materials and technical assistance protocols to guide the field site implementation and produce a limited number of prevention packages.
 - b. Identify at least one organization or field setting for the case study.
 - c. Develop a process evaluation plan.
- Recipient activities for the second year of activity include: Initiate and

complete the field site case study, initiate and complete the process evaluation, and revise training materials based upon the case study results. The program requirements for the second year include publishing and distributing results.

2. CDC Activities

- a. Host a meeting with the successful applicants within 60 days of the notice of grant award to discuss implementation of the project.
- b. Provide technical assistance in the general operation of this HIV prevention project.
- c. Consult on the choice of user for a case study with the prevention package.
- d. Monitor and evaluate scientific and operational accomplishments of this project through frequent telephone contact and review of technical reports and interim data analyses.
- e. Conduct site visits to assess program progress and mutually solve problems, as needed.

E. Application Content

Develop applications in accordance with PHS Form 5161-1 (OMB Number 0937-0189) and the instructions and format provided below.

Submit the original and two copies of PHS Form 5161-1 (OMB Number 0937-0189) and the original and two copies of the application. The application may not exceed 20 double-spaced pages, excluding abstract, table of contents, and appendices. Submit the original and each copy of the application *Unstapled Unbound*. Print all material double-spaced, in a 12-point or larger font size on 8 1/2" by 11" paper, with at least 1" margins, and printed on one side only. Provide a one-page abstract of the proposal and a complete table of contents to the application and its appendices. Beginning with the first page of text, number all pages clearly and sequentially. Number each page of the appendices also, e.g., for Appendix # 1, the pages should be numbered: A1-1, A1-2, A1-3. Replace double-sided article reprints with a one-sided copy.

Include a general introduction, followed by one narrative subsection for each of the numbered content elements per application, in the order in which the elements appear below. Label each narrative subsection with the element title and include all the information needed to evaluate that element of the application (except for curriculum vitae, references, and letters of support, which are appropriate for the appendices). The application content elements are:

1. Effective Behavioral Intervention

a. Identify the principal investigator(s) and name and location of the agency(ies) that originally developed, conducted, and evaluated the intervention research. Indicate whether the study was part of a multi-site project with multiple populations at risk.

b. Provide letters of support from original developers of the intervention other than the applicant (e.g., PIs at the other sites) indicating their intent to collaborate on a section of the intervention materials that will discuss generalizability of the intervention to other target populations or settings.

c. Where the applicant is not an original developer of the intervention, provide written permission from the intervention's original developers to develop and market materials for the prevention package.

d. Describe the study's positive results on behavioral or health outcomes, including how these results are both statistically and practically significant.

e. Include in the appendix a copy of any reports, that have been submitted for publication or published in peer reviewed journals, describing the study design and the positive behavioral or health outcomes of the intervention. This portion of the appendix should be labeled as "Intervention Study Design and Results."

f. Substantiate the need for a prevention package in terms of risk of target population and potential for generalizability to other target groups.

g. Describe the feasibility of implementation by other organizations, particularly those with limited resources.

2. Prevention Package

a. Describe the prevention package. Include descriptions of:

(1) The overall concept, format, and objectives, e.g., appropriateness for intended audience, description of intervention and the science behind it, target populations for whom the intervention would be appropriate;

(2) Pre-implementation phase, e.g., core elements related to this phase, time line of necessary steps, collaborators, training materials, material resources, facilities, staff (numbers, time, and skills), and cost categories for conducting the intervention;

(3) Implementation phase, e.g., core elements related to this phase, protocols for implementing the intervention and ensuring quality and consistency and providing technical assistance, identification of barriers to implementation and how they may be overcome, and process evaluation methods; and

(4) Maintenance phase, e.g., core elements related to this phase, how to deal with issues of staff turnover and retraining.

b. Explain how staff from HIV prevention programs (e.g., health departments and CBOs, and consumers) will be involved in the development of the package. Describe the planned procedures for how these collaborators will be identified.

c. Present a time line for developing the prevention package.

3. Plan To Identify Field Site(s) To Implement the Package in Year Two

a. Discuss a plan to identify and recruit potential users within your state (i.e., where the training and implementation and evaluation will be feasible within the budget constraints) and indicate any which already have shown interest in or may be interested in implementing this intervention.

b. Elaborate on the criteria and mechanism for selecting the user(s) who will implement the package.

Note: The agency that originally conducted the intervention is excluded from consideration as a potential user, as is any agency that currently or previously implemented the intervention.

4. Strategy to Assist Implementation

a. Describe the strategy to facilitate implementation of the package, including provision of training and direct technical assistance from the recipient to the selected user(s) and plans for assisting selected user(s) find additional funds, if relevant.

b. Discuss procedures to assist user(s) to implement the package, drawing upon the user's existing staff and resources, and to identify barriers to implementation and how to overcome them.

5. Plan To Evaluate the Implementation Process

a. Describe methods and measures to be used in assessing (1) Maintenance of the core elements during the intervention phases as specified in the prevention package, (2) quality of intervention delivery according to the methods described in the package, (3) quality of recipient's technical assistance and its delivery, (4) the impact of barriers to implementation on the case study (e.g., accuracy of record keeping, user's employee recruitment and retention, participant recruitment), (5) effectiveness of solutions to barriers, (6) costs of intervention delivery and cost containment strategies, and (7) maintenance of collaborative relationships. No behavioral or health outcomes are to be evaluated.

b. Describe plan to use the process evaluation results in finalizing the prevention package.

6. Capacity, and 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.

a. Demonstrate capacity to conduct the proposed activities including the process evaluation.

b. Clearly describe the proposed staffing, e.g., show percentages of each staff member's commitment to this and other projects, the division of duties and responsibilities for this project, brief position descriptions for existing and proposed personnel, and any partnerships with HIV prevention programs.

c. Demonstrate that the staff have the expertise to complete this project, including ability to produce the intervention package, e.g., include examples of previously developed fact sheets, web sites, or samples from other intervention packages.

d. Name the staff members who are key to the completion of the project. Provide a brief description of the strengths each brings to this project. Include their curriculum vitae in the appendix.

e. Describe access to graphics expertise for production and editing of the intervention package.

f. Describe equipment and facilities to be used for the proposed activities.

g. Briefly describe compliance regarding the inclusion of women, ethnic, and racial groups in the proposed activities.

7. Budget

Provide a detailed, line-item budget for the project; justify each line-item. Plan for at least two trips to Atlanta to meet with CDC representatives.

F. Submission and Deadline

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before July 20, submit the application to: Brenda Hayes, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 98089, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, NE, Room 3000, Atlanta, Georgia 30341-4146.

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. Effective Behavioral Intervention (20 Percent)

Clear demonstration of the effectiveness of the proposed intervention in a report that has been submitted for publication or has been published in a peer-reviewed journal. This is an absolute criterion. To be considered effective the intervention must have been tested using a control or comparison group with participants assigned randomly or without bias to study conditions, the data collection and analyses are completed, and the findings show significant positive results for changing HIV risk behavior or health outcomes. If this evidence is present, also consider:

a. The original research with this intervention was conducted and completed preferably with multiple target populations at multiple sites, especially with persons at increased risk of HIV infection.

b. The applicant addresses the feasibility of implementing the prevention package by organizations with limited resources.

2. Prevention Package (15 Percent)

Level of detail in the outline of the proposed package, for pre-implementation, implementation, and maintenance phases, e.g., for materials for the package itself, for training, and for technical assistance protocols. Clarity of described format, concepts, intended audiences, and objectives. Justification of the appropriateness of the package's objectives, format, and concepts to the intended users' needs and capabilities. Adequacy of planned input from HIV prevention programs into the development of the package. Adequacy of planned materials' review, pretesting, and revision. Adequacy of time scheduled for completing the proposed steps of the package's development.

3. Plan To Identify Field Site(s) To Implement the Package (10 Percent)

Recognition of which agencies are not eligible to implement the package. Quality of plan to identify eligible potential users which target populations for whom the intervention is appropriate and interest them in adopting the package during year two of the project. Selection of active methods

to identify and solicit potential users. Adequacy of criteria and mechanism for selecting the users to implement the package in year two.

4. Strategy To Assist Implementation (15 Percent)

Clarity of the strategy to assist selected users in adopting and implementing the behavioral intervention, e.g., training plan. Understanding of barriers to implementation and how to overcome them. Plan to assist selected users in implementing the intervention by using their existing resources and staff, e.g., provision of on-call technical assistance. Plan to help selected users find additional funds for implementing the package, if relevant.

5. Plan To Evaluate Implementation Process (15 Percent)

Feasibility and appropriateness of the applicant's plan to evaluate the selected user's implementation of the intervention as specified in the replication package. Thorough and realistic selection of process measures to evaluate.

6. Demonstrated Capacity, and 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 (25 Points)

a. Demonstrated Capacity.

Overall ability of the applicant to perform the proposed activities as reflected in their staff's and consultants' qualifications and availability. The extent to which the applicant demonstrates that proposed staff have experience with materials development and demonstrated familiarity with HIV behavioral interventions, particularly the intervention to be packaged. The nature of any partnership between researchers and HIV prevention programs. Adequacy of existing support staff, equipment, and facilities.

b. 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 includes:

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

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

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

4. A statement as to whether the plans for recruitment and outreach for study participants include the process 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 the funds. Extent to which the budget includes itemizations, justifications, scope, and deliverables for consultants or contractors.

H. Other Requirements

1. Technical Reporting Requirements

An original and two copies of semi-annual progress reports are required. Timelines for the semi-annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, CDC.

At the completion of two years of funding, recipients will be expected to share prevention packages with representatives of the original agencies that conducted the interventions on which the products are based, if different from those of the recipient.

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

AR98-1 Human Subjects Requirements

AR98-2 Requirements for Inclusion of Women, Racial and Ethnic Minorities in Research

AR98-4 HIV/AIDS Confidentiality Provisions

AR98-5 HIV Program Review Panel Requirements

AR98-7 Executive Order 12372 Review

AR98-8 Public Health System Reporting 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 sections 301 and 317(k), of the Public Health Service Act [42 U.S.C. 241 and

247b(k)], 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. Please refer to Program Announcement 99089 when you request information. See also the CDC home page on the Internet: <http://www.cdc.gov>. You may view or download this and other Program Announcements, and download application forms at this site.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Brenda Hayes, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 98089, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, NE, Room 3000, Atlanta, GA 30341, telephone (770) 488-2720, Email: bkh4@cdc.gov.

For program technical assistance, contact: 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-37, Atlanta, GA 30333, telephone (404) 639-1914, Email: rnk1@cdc.gov.

Please refer to Announcement number 99089 when requesting information and submitting an application.

Dated: June 1, 1999.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99098]

Strengthening HIV/AIDS and STD Prevention Through Use of Behavioral Data in Programmatic Decision Making; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999

funds for competitive cooperative agreement awards to (1) Better understand state and local decision-making processes that involve the use of HIV- and STD-related behavioral data, and (2) enhance the availability and utilization of high-quality HIV/STD behavioral data for meeting the needs of HIV/AIDS and STD prevention program planners. Use of scientifically credible behavioral data is expected to strengthen HIV/AIDS/STD prevention by enhancing decision makers' ability to target priority populations, precisely design programs that address local HIV risk factors, and respond quickly to changing prevention needs within their jurisdictions. This Program Announcement addresses the Healthy People 2000 priority areas of (18) HIV infection, (19) Sexually Transmitted Diseases, and (22) Surveillance and Data Systems.

Effective HIV/AIDS and STD prevention programs include the development, implementation, and evaluation of HIV behavioral risk-reduction interventions that address the specific needs of at-risk populations within their communities. To help achieve these objectives, public health decision makers need accurate, timely, and relevant data about HIV/STD risk behaviors and their determinants for groups within their jurisdictions. However, in some jurisdictions, HIV/STD behavioral risk data may be incomplete, unavailable, of poor quality, or out of date. In other areas, useful data are available but may not be effectively used in HIV and STD prevention program planning.

This process is intended to support research to answer several overarching questions: (1) How are HIV/AIDS/STD prevention decisions made? (2) How do behavioral data currently inform these decisions? (3) What gaps currently exist with respect to the match between available behavioral data and current decision-making needs? (4) What data and analyses can address key program decisions for setting community HIV/STD prevention priorities? (5) How can decision makers make better use of existing data? (6) In what measurable ways can HIV/STD prevention programs be improved by enhancements in the capacity of local decision makers to use behavioral data?

B. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam,

federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. In consultation with States, assistance may be provided to political subdivisions of States.

C. Availability of Funds

Approximately \$600,000 is available in FY 1999 to make up to 3 awards. CDC anticipates that the average award amount will range from \$180,000 to \$220,000 for the first year of the project. An application requesting more than \$220,000 (including indirect costs) will not be considered for review and will be returned to the applicant. Awards are expected to begin on or about September 30, 1999. Initial awards will be made for a 12-month budget period, with support anticipated for a project period of up to 4 years. Limited funds are anticipated to be available for the fourth year to support dissemination. These estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds may not be used to support laboratory testing; salary for medical personnel to perform clinical services; pharmaceuticals; or facility rental.

D. Program Requirements

In conducting activities to achieve the purpose of this Program Announcement, recipients will be responsible for activities under "Recipient Activities," and CDC will be responsible for the activities under "CDC Activities" listed below.

1. Recipient Activities

a. Phase I: Baseline Study Phase: Design and conduct a baseline study that systematically describes current HIV and STD prevention program decision-making processes in your jurisdiction, with specific attention to behavioral data. Focus should be on decision making by health departments and associated community planning groups and on the data used to support these purposes. Include evaluation of the data for decision making purposes in terms of its availability, scientific quality, and utility. Note gaps in data quality, availability, or interpretability that constrain decision making.

b. Meetings and Collaboration: Meet and collaborate with other recipients and CDC staff in the design, revision, and implementation of all aspects of the