

2. Technical Approach (30%)

a. The overall technical merit of the research plan and the soundness and scientific validity of the proposed hypoglycemia detection and monitoring system. The research plan must be thoroughly described and must include a detailed explanation of the operating principles of the technology to be developed.

b. The adequacy of the research plan includes the extent to which the applicant has adequately addressed all issues described under the Programmatic Interests section of this announcement and how well the evaluation plan can be used to effectively measure progress towards the stated objectives.

c. The background of the application, i.e., the basis for the present application, the critical evaluation of existing knowledge, and the specific identification of the knowledge gaps which the application intends to address.

3. Understanding the Problem (20%)

a. The applicant's understanding of the requirements, objectives, and interactions required for a successful research and development program.

b. The applicant must also present evidence of understanding of the difficult analytical problem presented by the complexity of individual variability in diabetes, and the unique challenges presented for non- or minimally-invasive detection or monitoring of hypoglycemia in different patient age groups.

c. The applicant must demonstrate an awareness and understanding of strengths and weaknesses of previous work related to the proposed technology.

4. Program Personnel (10%)

The extent to which the application has described:

a. The qualifications and commitment of the applicant including training and experience in chemistry, biochemistry, biomedical engineering, medicine, diabetology, or other relevant scientific disciplines

b. Detailed allocations of time and effort of staff devoted to the project

c. Information on how the applicant will develop, implement and administer the program

d. The qualifications of the support staff.

5. Collaboration (5%)

Collaboration is encouraged to accomplish the research objectives in a timely manner. The applicant should demonstrate the ability to collaborate

with other research centers, manufacturers, or commercial interests to conduct the described research and development plan.

6. Plans To Publicize the Research Effort (5%)

The applicants should provide an explanation of plans to encourage the publication of the research findings or otherwise make the information available to the public as soon as is feasible within the limits of protecting proprietary interests of the developer.

7. Human Subjects Protection (Not Scored)

Applications which do not adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects will be rejected.

8. Budget (Not Scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of grant funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual 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 the "Where to Obtain Additional Information" section of this announcement.

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

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317 of the Public Health Service Act, [42 U.S.C. section 241(a) and 247(b), as amended.] The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC homepage on the Internet at <http://www.cdc.gov> (click on funding).

Please refer to Program Announcement Number 99151 when requesting information. To receive an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Mattie B. Jackson, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2718, Email address: mij3@cdc.gov.

For program technical assistance, contact:

Dayton T. Miller, Ph.D., Centers for Disease Control and Prevention, 4770 Buford Highway (F-18), Atlanta, Georgia 30341, Telephone: (770) 488-4452, FAX: (770) 488-4541, EMAIL: dtm1@cdc.gov

or
Gary L. Myers, Ph.D., Centers for Disease Control and Prevention, 4770 Buford Highway (F-25), Atlanta, Georgia 30341, Telephone: (770) 488-4606, FAX: (770) 488-4192, EMAIL: glm1@cdc.gov

Dated: May 24, 1999.

John L. Williams,

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

[FR Doc. 99-13602 Filed 5-27-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99106]

Social and Environmental Interventions To Reduce HIV Incidence; 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 to identify social and environmental interventions to reduce HIV incidence. This program addresses

the "Healthy People 2000" priority areas of Educational and Community-Based Programs (Objective: Increase years of healthy life to at least 65 years) and HIV Infection (Objective: Confine annual incidence of diagnosed AIDS cases to no more than 43 per 100,000).

Prevention research has identified effective methods to help individuals change behavior to reduce their risk of acquiring or transmitting HIV. This research has contributed to significant decreases in risk and has saved many lives. However, an estimated 40,000 persons per year acquire HIV in the United States, so currently available methods are not sufficient and additional prevention approaches are needed. This announcement seeks research proposals to identify interventions in the social environment that could further reduce HIV incidence.

In 1988 the Institute of Medicine defined the mission of public health as "ensuring the conditions in which people can be healthy." Since then, many studies have identified societal characteristics that are associated with a variety of illnesses, but few studies have identified social or environmental interventions and evaluated their effectiveness. Early in the AIDS epidemic, members of affected communities reported that the social environment contributed to the incidence of disease. The contribution of the social environment can clearly be seen in countries where women's rights have not been protected, facilitating international trafficking in women for commercial sex. Stigma surrounding AIDS impedes many HIV prevention interventions. Environmental or structural conditions in the United States may also contribute to the incidence of HIV. Laws against carrying needles and syringes may encourage needle sharing by drug users. Laws that preclude recognition of same-sex partnerships may discourage long-term monogamous relationships among gay men or intimidate gay men so they cannot be reached with prevention interventions. A high concentration of liquor stores may foster environments where HIV and other sexually transmitted diseases flourish. Areas with low levels of community cohesion tend to have high rates of many different diseases.

This announcement seeks research applications to identify social and environmental interventions that could further reduce HIV incidence. Social and environmental factors that might be addressed include, but are not limited to: housing, legal issues, stigma, employment, physical environments of communities, and family and peer

support systems. The purpose of this research is not simply to add to the list of social and environmental conditions that may facilitate HIV transmission, but to also systematically examine the acceptability and feasibility of interventions to change the conditions, and to estimate the impact that the interventions might have on HIV incidence.

These research studies will: (1) Determine who is acquiring HIV in the community (use of relevant existing data is encouraged); (2) identify and document evidence of social and environmental factors that contribute to HIV incidence (using primary and secondary data analyses); (3) determine which social and environmental factors are amenable to specific interventions; and (4) assess the acceptability and feasibility of the identified interventions, and estimate the impact of the interventions on HIV incidence in a defined study population or geographic area. An important aspect of the study will be the participation of the affected community to identify their assessments of associations between social conditions and HIV infection, and of the acceptability and feasibility of proposed interventions. Study teams should be multi-disciplinary and include experts in sociology, epidemiology, human rights, and community organization and development. The goal of this announcement is to identify and develop social and environmental interventions to reduce HIV incidence and assess the acceptability, feasibility, and potential impact of those interventions. It is not anticipated that long-term interventions would be accomplished by this announcement. However, documenting the process of identifying and prioritizing interventions could facilitate implementation of interventions in the study community and other communities.

Jonathan Mann and others proposed a health and human rights framework for public health as a way to moving beyond the "paralyzing" effects of simply viewing poverty as the root cause of ill health. While not a requirement for these proposals, applicants might consider a human rights framework in their approach to identifying possible areas for intervention.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals,

other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. Small and minority owned businesses are encouraged to apply.

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

C. Availability of Funds

Approximately \$500,000 is available in FY99 to fund approximately 2-3 awards. It is expected that the average award will be \$200,000, ranging from \$150,000 to \$250,000, for a 12 month budget period within a two year project period. It is expected that awards will be made September 1, 1999. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Funding Preferences

In making awards, geographic and population risk group diversity will be considered.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under Recipient Activities. Because this is a cooperative agreement, there will be substantial federal involvement and CDC will be responsible for conducting activities listed under CDC Activities:

1. Recipient activities:

a. Develop a research protocol and plans for conducting this research in collaboration with CDC, and where appropriate, with the participation of State and local professional associations; community groups and organizations, especially those with a racial and ethnic minority membership and focus; HIV/AIDS service organizations; and organizations that serve persons at increased risk of HIV/AIDS.

b. Promote the development and evaluation of social and environmental interventions for HIV prevention by providing data and ongoing assistance to community planning groups; by disseminating data through publications and presentations by participating in project planning and implementation meetings; and by reporting ways in

which the data have been used to promote public health.

c. Establish procedures to maintain the rights and confidentiality of all study participants. Prior to implementation, this study must be submitted to the CDC Institutional Review Board (IRB) for review and approval or deferral.

d. Develop the review of existing information, research study protocol, and data collection forms.

e. In collaboration with the community, identify opportunities and needs for social and environmental interventions; assess the acceptability and feasibility of identified interventions; estimate the effectiveness of the interventions in preventing infection and disease.

f. Review existing information to evaluate the contribution of the social and environmental factors to the incidence of HIV, and potential opportunities for intervention.

g. Identify, recruit, obtain informed consent (when appropriate), enroll, and follow an adequate number of study participants as determined by study protocol and the program requirements.

h. Perform data analysis as determined in the study protocol.

(1) Share data with other collaborators to answer specific research questions.

(2) When appropriate, participate in multi-site data analysis and presentation and publication of research findings with collaborators.

(3) Prepare and submit for publication, a report of research findings describing the process of selecting and prioritizing interventions based on the acceptability, feasibility, and potential impact identified by this research.

2. CDC activities:

a. Provide technical assistance in the design and conduct of the research.

b. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project by an OPRR-approved IRB with either a single or multiple project assurance. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. As needed, assist in designing a data management system.

d. Coordinate research activities among the different sites, when appropriate.

e. Assist in the analysis of research information and the presentation and publication of research findings.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and

Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow the Evaluation Criteria in laying out your program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one inch margins, and unredacted font. Applications containing narratives that are longer than 25 pages will not be reviewed.

F. Submission and Application Deadline

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before August 1, 1999, submit the application to: Sheryl Disler, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99106, Centers for Disease Control and Prevention (CDC), Brandywine Road, Mail Stop E15, Room 3000, Atlanta, Georgia 30341-4146.

Deadline: Applications shall be considered as meeting the deadline if they are either received on or before the deadline date; or sent on or before the deadline date and received in time for Peer Review. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.) Applications that do not meet these criteria are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent peer reviewer group appointed by CDC. Applications will be reviewed and evaluated only on the basis of the evidence submitted.

1. Background and Objectives (15 points): Demonstrated scientific significance of the proposed study in that it will publish data not otherwise available concerning social and environmental interventions to reduce HIV incidence.

The application should include a detailed review of the scientific literature pertinent to the study being proposed, with evidence for the relationship of social and environmental factors to the incidence of HIV. This literature review should suggest specific research questions that will guide the research. The goals and objectives for

the research should be clearly stated along with how findings from this study could be used to implement social and environmental interventions.

2. Site Selection (20 points):

Demonstration of a high prevalence of HIV or AIDS in the study area. Demonstrated capacity to access the relevant study community or communities.

The application should include a description of the size and characteristics of the communities proposed for study. Describe the prevalence and estimated incidence of HIV infection in the study community. Include the age, gender, race/ethnicity, and HIV-risks of persons with HIV in the community to be studied. Describe the potential for community participation to identify interventions and participate in the assessment of their acceptability, feasibility, and estimated impact. Describe the experience of the investigators in working with communities in a culturally and linguistically appropriate manner. Letters of support from cooperating organizations should be included which detail the nature and extent of such cooperation.

3. Methods (25 points):

Appropriateness of methods for identifying social and environmental interventions to reduce HIV incidence and measuring the acceptability, feasibility and potential impact of the interventions within a community or geographic area.

The application should describe the approach to gathering information on the potential contribution of social and environmental factors to HIV incidence in the study area, including anticipated primary and secondary data collection. It should specify quantitative and qualitative analytic techniques to be used to develop an intervention and evaluate its acceptability, feasibility, and potential impact. The application should also outline the methods and rationale that will be used in the study to assess acceptability, feasibility, and estimate impact of possible interventions, including the plan for involving members of the affected community. The percentage-time commitments, duties, and responsibilities of project personnel should be sufficient to operationalize the proposed methodology.

4. Research Capacity (20 points):

Experience in similar social interventions, human rights evaluations, and HIV prevention research; and availability of qualified and experienced personnel.

The application should describe the capacity and experience of the research

team and should include CVs and position descriptions for key staff and project participants. Letters of support from key collaborators and community groups should be included.

5. Evaluation Plan (15 points): Appropriateness and comprehensiveness of: (a) the schedule for accomplishing the activities of the research; (b) an evaluation plan that identifies methods and instruments for evaluating progress in implementing the research objectives; and (c) a proposal to complete and submit for publication, a report of research findings.

The application should include time-phased and measurable objectives. The proposed report of research findings should address a plan for documenting the process of identifying and prioritizing interventions based on acceptability, feasibility, and estimated impact within a defined community or population.

6. Confidentiality (5 points): Appropriateness of the plan to protect the rights and confidentiality of all participants, including 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 proposed justification when representation is limited or absent.

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

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

7. Budget (not scored): The extent to which the budget is reasonable, clearly justified, and consistent with the intent of the announcement.

The 12 month budget should anticipate the organizational and operational needs of the study. The budget should include staff, supplies, and travel (including two trips per year for up to four members of the study team to meet with CDC staff and other investigators).

8. Human Subjects: Does 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. Progress reports (semiannual);
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: Sheryl Disler, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mail Stop E15, Atlanta, GA 30341-4146.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I 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-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

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

J. Where To Obtain Additional Information

Please refer to Program Announcement 99106 when you request information. For a complete program description, information on application procedures, an application package, and business management technical assistance, contact: Sheryl Disler, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99106, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mail Stop 15, Atlanta, GA 30341-4146, Telephone (404) 842-488-2756; Email: sjd9@cdc.gov.

See also the CDC home page on the Internet: [HTTP://WWW.CDC.GOV](http://WWW.CDC.GOV).

For program technical assistance, contact Catherine Avery, Mailstop E46, CDC, Atlanta, GA 30333, 404-639-6191, cla2@cdc.gov.

Dated: May 24, 1999.

John L. Williams,

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

[FR Doc. 99-13605 Filed 5-27-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99136]

State-Based Core Injury Program Development; 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 State-Based Core Injury Program Development. This program addresses the "Healthy People 2000" priority area(s) of Unintentional Injuries, Violent and Abusive Behavior, and Surveillance and Data Systems. The purpose of the program is to allow State public health agencies with minimal injury prevention and control capability to develop or strengthen their organizational focus in the prevention and control of injuries. State public health agencies with a minimal injury prevention capacity are those which do not possess some combination of the following features and tools: a coordinator for injury activities; an up-to-date profile of injuries within the State from existing data sources; an advisory structure to utilize collaborative relationships with public and private sector groups; organizations, agencies and individuals with interest or expertise in injury prevention or control; a current priority-driven State plan for injury prevention and control.

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.

States funded previously under Program Announcement 780, Part II, Basic Injury Program Development, may not apply under this announcement.