Wyoming

Sheryl Jeffries, State Single Point of Contact, Herschler Building 4th Floor, East Wing, Cheyenne, Wyoming 82002, Telephone: (307) 777–7574, FAX: (307) 638–8967.

Territories

Guam

Mr. Giovanni T. Sgambelluri, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone: 011–671–472–2285, FAX: 011–671–472–2825.

Puerto Rico

Norma Burgos/Jose E. Caro, Chairwoman/Director, Puerto Rico Planning Board, Federal Proposals Review Office, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–1119, Telephone: (809) 727–4444; (809) 723–6190, FAX: (809) 724–3270; (809) 724–3103.

North Mariana Islands

State Single Point of Contact, Planning and Budget Office, Office of the Governor, Saipan, CM, North Mariana Islands 96950.

Virgin Islands

Jose George, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802.

Please direct all questions and correspondence about intergovernmental review to: Linda Clarke, Telephone: (809) 774–0750, FAX: (809) 776–0069.

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Centers for Disease Control and Prevention

[Announcement Number 625]

FY 1996 Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program for epidemiologic and behavioral research studies of AIDS and HIV infection. These include studies to examine factors related to disease progression of HIV infection in women, mother-to-child HIV transmission, sexual and needleborne transmission of HIV among drug users, and the spread of HIV infection in rural and small cities in the United States. The study of these research areas as they pertain to racial and ethnic minority populations (defined as Black, Hispanic, Asian and Pacific Islander, and American Indian) is encouraged because minorities constitute over 50% of all reported cases of AIDS and approximately 76% of all women and children with AIDS.

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 HIV Infection. (To order a copy of ''Healthy People 2000,'' see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a) and 247b(k)(2)], as amended. Applicable program regulations are set forth in 42 CFR Part 52, entitled ''Grants for Research Projects.''

Smoke-Free Workplace

CDC strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and 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. This is consistent with the PHS mission to protect and advance the physical and mental health of American people.

Eligible Applicants

Eligible applicants include all public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, and other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- 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 $6,900,000 will be available in FY 1996 to fund approximately 16 awards. It is expected that the average new award will be approximately $300,000 and that the average continuation award will be $500,000, ranging from $100,000 to $1,000,000. It is expected that approximately 3 new and 13 competing renewal awards will be made and that awards will begin on or about September 30, 1996. Awards will be funded 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 the project period will be made on the basis of satisfactory programmatic progress and the availability of funds.

Purpose

The purpose of these awards is to help support researchers in the conduct of HIV-related epidemiologic and behavioral research studies. These include studies to examine factors related to disease progression of HIV infection in women, mother-to-child HIV transmission, sexual and needleborne transmission of HIV among drug users, and the spread of HIV infection in small cities and rural areas in the United States. The study of these research areas as they pertain to minority populations are of special interest.

Research Issues

Four research issues of programmatic interest to the health care community and to CDC for FY 1996 are listed below and are considered of significant importance in gaining a greater understanding of the epidemiology of AIDS and HIV infection. However, applications submitted by organizations that examine additional important HIV-related epidemiologic research issues will also be accepted and considered for funding.

Applicants addressing the same research issue should be willing to participate in collaborative studies with other CDC-sponsored researchers, including the use of common data collection instruments, specimen collection protocols, and data management procedures. Applicants are required to identify their proposed research issue on line 1 of the face page of the application if the PHS–398 is used, or Block 11 of the face page if the PHS–5161–1 is used (for more information on the forms to use, see the section **APPLICATION SUBMISSION AND DEADLINE**).

1. Studies of HIV Disease Progression in Women

Studies should be designed to identify, enroll, and prospectively follow women who are HIV-infected and demographically similar women who are not HIV-infected but who have demonstrable risk for HIV infection so that the biologic, behavioral, and psychosocial determinants and correlates of HIV disease progression

and other health outcomes can be assessed. Preference will be given to sites (1) where at least 200 HIV-infected and 100 HIV-uninfected women are already being systematically followed, (2) at which behavioral scientists are part of the research team, and (3) at which the applicant or its documented collaborative partners have the ability to perform virologic and immunologic assays. Applicants must demonstrate that they can provide adequate rates of follow-up, including collection of laboratory specimens, tracking and abstraction of medical records, and determination of causes of deaths. Applicants must be willing to participate in collaborative studies with other CDC-sponsored women's HIV disease progression projects, including the use of common data collection instruments, specimen collection protocols, and data management procedures. Applicants must demonstrate cost-efficient local data management and statistical capability.

2. Mother-to-Child HIV Transmission Studies

Studies should be designed to identify HIV-infected women during pregnancy or at delivery and enroll the women and their infants in a prospective follow-up study to examine factors related to mother-to-child HIV transmission, early diagnosis of infant infection, and disease progression in children. Studies designed to examine the effect of interventions such as zidovudine use to prevent mother-to-child HIV transmission are of particular interest. Preference will be given to applicants with studies in which mother-infant pairs are already being systematically identified and followed, and which have the ability to perform virologic and immunologic assays. Applicants must demonstrate that they can provide adequate rates of follow-up of both mothers and infants, including collection of laboratory specimens at periodic intervals (particularly within the first 48 hours of birth and during the first 6 months of life), and long-term follow-up of infants, including those placed in foster care. Applicants must be willing to participate in collaborative studies with other CDC-sponsored mother-to-child HIV transmission projects, including use of common data collection instruments and study design where warranted. Applicants must demonstrate cost-efficient data management, laboratory testing, and statistical capability or provide explicit plans for data management by CDC or an outside group. Applicants must demonstrate the ability to enroll and follow at least 30 HIV-positive mother-infant pairs per year.

3. Sexual and Needleborne Transmission of HIV Among Drug Users

Study proposals are solicited that address HIV infection in young drug-abusing populations that are recruited on the street and not routinely seen in clinics, hospitals, or similar institutional settings. The purpose of such studies will be to address issues important to the sexual, needleborne, and injection paraphernalia related transmission of HIV and settings that may contribute to HIV infection among drug users who are not seen in the usual medical and drug-treatment facilities. Preference will be given to projects that involve community outreach to enroll recently initiated drug users for interview and examination and that focus on inner-city or rural areas where drug use among young adults is prevalent.

Examples of worthwhile proposals are HIV seroincidence cohorts that describe initiating practices of injection and risks for young adults; current sources, acquisition, and cleaning and disposal of needles and syringes; issues of violence as they relate to drug use and the impact on individual, family and community; social networks including contacts and community dynamics that affect HIV incidence. Other related aspects of incidence and management of infectious complications of drug use, including skin and respiratory infections that could be altered by HIV immune suppression, and their possible impact on the progression of HIV infection. Applicants should demonstrate their ability to access young injection drug-using populations not currently in drug treatment, interview and examine them in a confidential manner, and provide or link study participants to appropriate medical, drug-treatment and other services. Applicants for studies of these difficult-to-reach populations should demonstrate their ability to provide new insights into the epidemiology of HIV infection in injecting drug users and not duplicate other projects; possess cost-effective data management and statistical capabilities, or provide specific plans for management of data; and participate collaboratively in a multisite study with other researchers in the development, implementation, and analysis of data from the proposed study.

4. HIV Infection in Small Cities and Rural Areas

Studies should be designed to identify, interview, and learn more about HIV-infected persons who live in rural and small cities (small cities and rural areas outside metropolitan statistical areas of more than 500,000) such as their (1) modes of exposure to HIV, (2) substance abuse, (3) travel/migration patterns, (4) health care seeking behaviors, (5) barriers to care, and (6) sexually transmitted diseases. Preference will be given to studies that address the following questions. What specific behaviors (e.g., sexual and substance abuse) are related to infection of persons residing in these areas? Did persons from these areas become infected in their current areas of residence or during travel or residences in large metropolitan areas? What are the barriers to care specific to HIV-infected persons living in small cities and rural areas? What health care sites (e.g., STD and family planning clinics) did the patient visit during and before the estimated time period of infection, and what HIV prevention messages and services were offered and received?

Applicants must demonstrate the ability to enroll and follow at least 50 HIV-infected patients residing in small cities and rural areas. Applicants must be willing to participate collaboratively in a multi-site study with other researchers in the development, implementation, and analysis of data from the proposed study. Applicants are expected to determine proper distribution of participants by sex, race, and ethnicity for their topic of study and to state clearly in the application the composition of the proposed study population. If women, racial, or ethnic minorities are not included in the proposed study, applicants must justify their exclusion.

Program Requirements

Under this cooperative agreement program, CDC will assist the researcher in conducting the epidemiologic research of AIDS and HIV infection described in the **PURPOSE** section of this announcement.

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities listed under subparagraph 1., below, and CDC shall be responsible for the activities listed under subparagraph 2., below:

1. Recipient Activities

Applicants addressing the same research issue must be willing to participate in collaborative studies with other CDC-sponsored researchers, including the use of common data collection instruments, specimen collection protocols, and data management procedures.

a. Meet with other funded grantees and develop the research study protocol and the interview instrument.

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

c. Continue to follow study participants as determined by the study protocol.

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

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

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

g. Conduct data analysis with all collaborators as well as present research findings subject to the provisions of the following section, CDC Activities.

2. CDC Activities

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

b. Provide technical guidance in the development of study protocols, consent forms and questionnaires.

c. Assist in designing a data management system.

d. Perform selected laboratory tests.

e. Coordinate research activities among the different sites.

f. Participate in the analysis of research information and the presentation of research findings.

Evaluation Criteria

All applications will be reviewed according to the same criteria; however, applicants will be ranked on a scale of 200 maximum points according to the four research issues listed above and a fifth category for all other HIV-related epidemiologic studies. All applicants must state which research category they are addressing. Applications should demonstrate the applicant's ability to address the research problem in a collaborative manner with CDC. Applications will be reviewed and evaluated based on the evidence submitted, which specifically describes the applicant's abilities to meet the following criteria:

1. The inclusion of a detailed review of the scientific literature pertinent to the study being proposed and specific research questions or hypotheses that will guide the research; (25 points)

2. The originality and need for the proposed research, the extent to which it does not replicate past or present research efforts, and how findings will be used to guide prevention and control efforts; (25 points)

3. The quality of the plans to develop and implement the study describing how study participants (including racial and ethnic minority populations) will be identified, enrolled, tested and followed; (25 points)

4. The ability to enroll and follow an adequate number of eligible study participants to ensure proper conduct of the study. This includes demonstration of the availability of HIV-infected potential study participants and the experience of the investigator in enrolling and following such persons in a culturally and linguistically appropriate manner; 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 community(ies) and recognition of mutual benefits will be documented; (25 points)

5. The applicant's understanding of the research objectives and the ability, willingness, and need to collaborate with CDC and researchers from other study sites in study design and analysis, including use of common forms, and sharing of specimens (when appropriate) and data; (25 points)

6. The applicant's current experience in AIDS and HIV epidemiologic or behavioral research and how it will be applied to achieving the objectives of the study (letters of support from cooperating organizations that demonstrate the nature and extent of such cooperation should be included); (20 points)

7. The comprehensiveness of the plan to protect the rights and confidentiality of all participants; (20 points)

8. Availability of qualified and experienced personnel with realistic and sufficient percentage-time commitments; clarity of the described duties and responsibilities of project personnel; adequacy of the facilities, equipment, and plans for the administration of the project, including project oversight and data management; (20 points)

9. A comprehensive schedule for accomplishing the activities of the research and an evaluation plan that identifies methods and instruments for evaluating progress in designing and implementing the research objectives. (15 points)

10. *Other* (Not Scored).

(1) *Budget*

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

(2) *Human Subjects*

Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (a) protections appear adequate and there are no comments to make or concerns to raise, or (b) protections appear adequate, but there are comments regarding the protocol, or (c) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Funding Preferences

Priority will be given to competing continuation applications from satisfactorily performing projects over applications for projects not already receiving support under the program. Projects will be awarded so that the composite of projects represents the geographic and demographic characteristics of the HIV-infected population.

Executive Order 12372 Review

Applications are not subject to review under Executive Order 12372, Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.943, Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups.

Other Requirements

1. 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.

2. Human Subjects

This program involves research on human subjects. Therefore, all applicants 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 or activity 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.

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 with or support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

3. HIV/AIDS Requirements

Recipients must comply with the document entitled Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

4. Patient Care

Applicants should provide assurance that all HIV-infected patients enrolled in their studies will be linked to an appropriate local HIV care system that can address their specific needs such as medical care, counseling, social services, and therapy. Details of the HIV care system should be provided, describing how patients will be linked to the system. Funds will not be made available to support the provision of direct care for study participants.

5. Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-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. 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, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

Application Submission and Deadline

The original and five copies of the completed application packet PHS 398 (Revised 5/95, OMB No. 0925–0001) must be submitted to Van Malone, Grants Management Officer (ATTN: Kevin Moore), Grants Management Branch, Procurement and Grants Office (625), Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 320, Mail Stop E–15, Atlanta, Georgia 30305, on or before August 2, 1996. States and local governments may use Form PHS–5161–1 (Revised 7/92, OMB No. 0937–0189); however, Form PHS–398 is preferred. If using Form PHS–5161–1, submit an original and two copies to the address stated above.

1. Deadline

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

a. Received on or before the stated deadline date; or

b. Sent on or before the deadline date and received in time for submission to the independent review group. (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 accepted as 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

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Kevin Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 320, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6550, E-mail address kgm1@opspgo1.em.cdc.gov. 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.

Programmatic technical assistance may be obtained from Jeff Efird, Division of HIV/AIDS Prevention, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mail Stop E–45, Atlanta, Georgia 30333, telephone (404) 639–6130. Eligible applicants are encouraged to call before developing and submitting their application. Please refer to Announcement Number 625 when requesting information.

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 from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

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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