

e. Obtain assurances of confidentiality by agencies to which referrals are made. Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A DHHS certificate of confidentiality may be required for some projects.

D. Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) to ensure that individuals of 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 a clear and compelling rationale exists 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 47949-47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB Number 0937-0189) must be submitted to Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, on or before July 22, 1997.

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

1. Received on or before the deadline date, or
2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicant must request a legible dated U.S. Postal Service postmark or obtain a legible dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable proof of timely mailing.)

B. *Late Applications:* Applications which do not meet the criteria in A.1. or 2., are considered late applications.

Late applications will not be reviewed 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 your name, address, and phone number and will need to refer to Announcement 746. A complete program description and information on application procedures are contained in the application package. Business management technical assistance, and an application package may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-13, Atlanta, Georgia 30305, telephone (404) 842-6535; Internet: jcw6@cdc.gov.

FAS programmatic assistance may be obtained from Dr. Louise Floyd at telephone (770) 488-7370, Internet: rlf3@cdc.gov, or Gregg Leeman at telephone (770) 488-7268, Internet: gcl1@cdc.gov, Division of Birth Defects and Developmental Disabilities, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-15, Atlanta, Georgia 30341-3724.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is [http://www.cdc.gov].

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 746 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.

Dated: May 16, 1997.

Joseph R. Carter,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 745]

Cooperative Agreement for Population-Based Surveillance of Fetal Alcohol Syndrome; Notice of Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement program to establish or enhance statewide, population-based surveillance of fetal alcohol syndrome (FAS). Population-based surveillance of FAS is important to document the magnitude of the problem and to monitor trends in the occurrence of this preventable birth defect. Ongoing surveillance is also essential in documenting the impact of prevention efforts.

CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Alcohol and Other Drugs, Environmental Health, Maternal and Infant Health, and Surveillance and Data Systems. (To order a copy of "Healthy People 2000," see section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under Sections 301 and 317(k)(2) of 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 non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are the State health departments or other State agencies or departments deemed most appropriate by the State to direct and coordinate the State's surveillance activities and that: (1) represent a population of not less than 25,000 live births per year within

a State, group of States, or geographically-defined area; and/or (2) demonstrate evidence of alcohol problems among women in the targeted study population.

This eligibility includes bona fide agents or instrumentalities of States which are acting as the official agent of the State(s) for surveillance activities.

This eligibility also includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

State agencies applying under this announcement that are other than the official State health department must provide written concurrence for the application from the official State health agency.

Only one application from each single State or group of States may enter the review process and be considered for an award under this announcement.

Note: Effective January 1, 1996, Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately \$300,000 will be available in FY 1997 to award up to 3 cooperative agreements. Projects are expected to begin on or about September 30, 1997, and will be 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 the approved project period will be made on the basis of satisfactory progress and the availability of funds.

Use of Funds Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subcontractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal

funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or "grass roots" lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104-208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104-208 (September 30, 1996).

Background

Birth defects are the leading cause of infant mortality in the United States, accounting for more than 20 percent of all infant deaths. In addition, birth defects are the fifth leading cause of years of potential life lost and contribute substantially to childhood morbidity and long-term disability. Fetal Alcohol Syndrome is a leading birth defect that causes significant lifetime disability. Unlike many other birth defects, however, FAS has a known etiology and is preventable. The success of any public health prevention or intervention program must be measured by comparing the incidence or prevalence of a condition before and after implementation of programs. Incidence and prevalence data are also important for estimating the societal impact of a disorder and planning for resource use.

The specific Healthy People 2000 health objective is to reduce the rate of FAS in the general population to no more than .12 cases per 1,000 live births by the year 2000. The original baseline data for this objective (.22 per 1,000 live births in 1987) were derived from a national hospital-based epidemiologic

surveillance program of birth defects—the Birth Defects Monitoring Program (BDMP) of CDC. Although more recent rates of .67 per 1,000 have been generated by this system, this increase probably represents improvements in the recognition and reporting of FAS at birth. Other studies using different methods and data sources report prevalence rates ranging from .33 to 2.2 per 1000.

Developing a surveillance system for FAS presents unique challenges that cannot be met by current birth defects monitoring systems that focus only on the first year of life. There is no simple, objective laboratory test for the diagnosis of FAS. The diagnosis is based primarily on clinical examination and the application of diagnostic criteria in each of three categories: (1) prenatal or postnatal growth retardation; (2) central nervous system abnormalities which may manifest as developmental delays in childhood; and (3) characteristic abnormal facial features (including short palpebral fissures, a long smooth philtrum, thin upper lip, and flattened midfacial area). Since no single characteristic (beyond the facial dysmorphism) is specific to the diagnosis of FAS, the application of these criteria requires expertise in recognizing dysmorphic features and differentiating this condition from other syndromes and malformations.

Furthermore, some of the cardinal facial features and central nervous system abnormalities are not apparent during the first year of life. FAS, like other syndromes, becomes easier to diagnose with increasing age, at least until about puberty.

Clearly, surveillance of FAS cannot depend on any single source for case ascertainment. A multiple source method which may include, but is not limited to, birth defects monitoring programs, developmental disabilities or special needs registries, hospital discharge data, special education and other school records, Medicaid data, vital statistics, private provider and special diagnostic units, screening and case-finding activities in special settings, and other population-based systems appear promising. The theoretical basis for this multiple-source approach is that children with FAS, because of the nature of the health and developmental problems associated with the condition, are likely to encounter one or more of these resources for services at some point in early childhood or school age. Oftentimes, however, the correct diagnosis is not made. Thus, an integral component of a multiple-source methodology is provider education and training.

Purpose

The purpose of this cooperative agreement is to:

A. Enhance an existing system or to develop and implement a new system which uses a multiple source surveillance methodology to enable researchers to determine the prevalence of FAS within a geographically-defined area (statewide, multiple States, or regions of a State);

B. Improve the capacity to ascertain true cases of FAS and generate population-based surveillance data;

C. Establish relationships with facilities or programs where children with FAS are likely to be diagnosed or receive services, such as high-risk newborn registries, special diagnostic units, special education programs, special needs registries, and other programs or settings for children with developmental disabilities;

D. Evaluate the completeness of the surveillance system methodology, the system's ability to generate a prevalence rate for FAS, and the potential for monitoring trends;

E. Implement provider training and education on FAS to improve case ascertainment, referral and case management practices, and prevention activities.

Program Requirements

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

A. Recipient Activities

1. Meet at CDC to:

a. Develop and agree on a surveillance case definition.

b. Develop and agree on a plan to implement the data collection instruments and methods for abstracting medical and school records as appropriate.

c. Develop an evaluation plan for the surveillance system. This will include a plan for estimating false positive and false negative error rates, such as a comparison of cases identified using the surveillance criteria with more comprehensive clinical criteria or follow-up of cases to confirm the diagnosis.

d. Develop a plan for publishing prevalence rates and rates among various risk groups and authorship on other publications emanating from the surveillance activities.

2. Develop and implement a multiple source methodology to ascertain cases of

FAS and generate population-based estimates of the prevalence of FAS.

3. Develop a plan for provider education and training on FAS case ascertainment.

4. Establish collaborative relationships (for the purpose of diagnosis and case ascertainment) with appropriate diagnostic units serving the surveillance population, such as special genetics, dysmorphology, neurobehavioral, and developmental pediatrics clinics.

5. Establish collaborative relationships with agencies providing services to children with FAS including special education, foster care programs, high-risk newborn nurseries, and other high-risk service environments.

6. Implement quality assurance procedures to ensure that study protocols are being followed, and that the surveillance procedures are being uniformly implemented in the study sites.

7. Collaborate with other participating sites on a manuscript which describes the surveillance system, case definitions, methodology, collaborative relationships, data collection, findings (including the prevalence rate of FAS), and recommendations across sites.

B. CDC Activities

1. Convene two meetings of awardees in the first nine months, then annually thereafter, to develop and review the surveillance case definition, design surveillance data collection instruments, and develop study protocols and procedures.

2. Provide leadership and current scientific information on relevant health information and surveillance approaches, and provide oversight of the surveillance and research design to ensure adherence to appropriate standards.

3. Provide guidance and technical assistance in the development of an evaluation plan for the surveillance system.

4. Conduct periodic site visits to observe and discuss development and implementation of activities and analysis of surveillance data.

5. Provide guidance and coordinate the aggregation and analysis of data across surveillance sites.

6. Maintain multi-state data base to develop FAS prevalence rates and other information for reports and other publications, when appropriate.

7. Cooperate in preparation and publication of study results.

Technical Reporting Requirements

An original and two copies of semiannual progress reports are

required of all awardees. Time lines for the semiannual reports will be established at the time of award. An original and 2 copies of the Financial Status Report (FSR) are required no later than 90 days after the end of the budget period. A final program report and FSR are due no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Application Content

Applications must be developed in accordance with PHS Form 5161-1 (Revised 7/92, OMB Number 0937-0189). All material must be typewritten, double-spaced pages, with type no smaller than 10 CPI (12 point), on 8.5" x 11" paper, with at least 1" margins, headings, and footers, unbound and printed on one side only. Number each page clearly, and provide a complete index to the application and appendices. Do not include any spiral or bound materials or pamphlets. All graphics, maps, overlays, etc., should be in black and white and meet the above criteria.

The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities. Do not include a detailed budget or detailed budget justification as part of the Program Narrative.

A. Abstract

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director and telephone number. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicant's organization and composition. The abstract should precede the Program Narrative. The abstract should include the required cohort statistics and eligibility status.

B. Program Narrative (not to exceed 25 pages)

The Program Narrative should specifically address all items in the "PROGRAM REQUIREMENTS." All items of the Program Narrative should begin on a new page. If the proposed program is a multiple-year project, the applicant should provide detailed description of the first-year activities, and briefly describe future-year objectives and activities. The "EVALUATION CRITERIA" will serve as the basis for evaluating the

application; therefore, the narrative of the application should address the following:

1. Applicant's Understanding of the Problem

The applicant should demonstrate an understanding of FAS, the challenges to conducting surveillance of FAS and other conditions associated with prenatal alcohol use, and an understanding of the applicant's abilities and resources to conduct FAS surveillance.

2. Applicant's Description of the Surveillance Methodology

The applicant's description should include at least the following:

- a. A proposed surveillance case definition and how the definition will be operationalized given the described methodology;
- b. Clearly described methods for case ascertainment using multiple sources. Methods should include a plan for estimating the completeness of the surveillance system including a plan for estimating sensitivity and specificity;
- c. Demonstration of a minimum annual birth population of not less than 25,000 in the State or region to be included in the study and/or evidence of unusually high rates of alcohol use among women in the population (e.g., analysis of BRFSS, PRAMS, or other local surveys) from which the surveillance data will be generated;
- d. Methods for collaboration with and written assurances from special diagnostic units such as genetics clinics, developmental disabilities registries, special education programs, and other agencies serving children who may have FAS;
- e. Collaboration with existing state-based birth defects, developmental disabilities, or FAS surveillance activities;
- f. A description of the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

3. Project Management and Staffing

The applicant must demonstrate the ability and expertise to carry out population-based surveillance for FAS. The applicant must demonstrate the following:

3. Project Management and Staffing

The applicant must demonstrate the ability and expertise to carry out population-based surveillance for FAS. The applicant must demonstrate the following:

- a. Expertise in abstracting medical and school records;
- b. Expertise in the diagnosis of FAS;
- c. Expertise in epidemiology and public health surveillance;
- d. Plan for personnel resources to be allocated to the project to achieve the goals and objectives of the application (dedication of at least one full-time

professional, scientific employee or equivalent to the project is strongly advised).

4. Relationship to Other Funding Sources

The applicant must describe the availability of State resources and other sources of funds to support the surveillance activities in this cooperative agreement. The applicant must describe how its program will build on existing surveillance, screening, diagnosis, or service-related activities for FAS.

5. Budget Justification and Adequacy of Facilities

This section must include a detailed first-year budget narrative justification with future annual projections. Budgets should include costs for travel for two project staff to attend at least two two-day meetings in Atlanta with CDC staff. The applicant should describe the program purpose of each budget item. Proposed contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection.

6. Human Subject Review

This section must describe how the project will be subject to initial and continuing review by the appropriate human subjects institutional review committees.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Understanding of the Problem (20%)

The extent to which the applicant has a clear, concise understanding of the requirements, objectives, and purpose of the cooperative agreement, including the applicant's willingness to collaborate and coordinate activities with CDC and other funded sites. The extent to which the application reflects an understanding of the complexities of FAS surveillance and an understanding of the necessary resources to conduct this surveillance.

B. Description of the Surveillance Methodology (50%)

The extent to which the applicant describes an approach to surveillance of FAS that demonstrates collaboration with multiple sources (letters of support encouraged) and addresses all issues outlined in the "Program Requirements"

recipient activities section. In addition to these program requirements, the extent to which the applicant addresses the six issues outlined under section 2 of the "Program Narrative" regarding the surveillance methodology.

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. 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; and
- (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

C. Project Management and Staffing (30%)

The extent to which the applicant has the skills, experience, and access to data that demonstrate the ability to conduct FAS surveillance. The extent to which the applicant addresses the issues described in the "Program Narrative" section 3. The adequacy of the description of the present staff and capability to assemble competent and trained staff to conduct FAS surveillance. The applicant shall identify all current and potential personnel who will be utilized to work on this cooperative agreement, including qualifications and specific experience as it relates to the requirements set forth in this request.

D. Budget Justification and Adequacy of Facilities (not scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant shall describe and indicate the availability of facilities and equipment and other sources of funds necessary to carry out this project.

E. Human Subject Review (not scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

Funding Preferences

In making awards, priority consideration may be given to: (1)

ensuring a racial/ethnic balance; and (2) ensuring rural, urban, and national geographic distribution among the grantees.

Executive Order 12372

Applications are subject to the 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 of each affected State or tribe. 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 forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, no later than 60 days after the application deadline date. The granting agency does not guarantee to "accommodate or explain" 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 CDC, they should forward them to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, no later than 60 days after the application deadline date. The granting agency does not guarantee to "accommodate or explain" tribal process recommendations it receives after that date.

Public Health System Reporting Requirement

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 93.283.

Other Requirements

A. Paperwork Reduction Act

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

B. Human Subjects

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

C. Confidentiality

All personal identifying information obtained in connection with the delivery of services provided to any person in any program carried out under this cooperative agreement cannot be disclosed unless required by a law of a State or political subdivision or unless such a person provides written, voluntary informed consent.

1. Nonpersonal identifying, unlinked information, which preserves the individual's anonymity, derived from any such program may be disclosed without consent:

- a. In summary, statistical, or other similar form, or
- b. For clinical or research purposes.

2. Personal identifying information: Recipients of CDC funds who must obtain and retain personally identifying information as part of their CDC-approved work plan must:

- a. Maintain the physical security of such records and information at all times;
- b. Have procedures in place and staff trained to prevent unauthorized

disclosure of client-identifying information;

1c. Obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made. Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A DHHS certificate of confidentiality may be required for some projects.

D. Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) to ensure that individuals of 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 a clear and compelling rationale exists 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 47949-47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB Number 0937-0189) must be submitted to Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, on or before July 22, 1997.

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

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the special emphasis panel review committee. For proof of timely mailing, 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 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. Late applications will not be considered 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 your name, address, and phone number and will need to refer to Announcement 745. A complete program description and information on application procedures are contained in the application package. Business management technical assistance, and an application package may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E-13, Atlanta, Georgia 30305, telephone (404) 842-6535; Internet: jcw6@cdc.gov.

FAS surveillance technical assistance may be obtained from Karen Hymbaugh at telephone (770) 488-7370, Internet: kxh5@cdc.gov, or programmatic assistance from Gregg Leeman, at telephone (770) 488-7370, Internet: gcl1@cdc.gov, Division of Birth Defects and Developmental Disabilities, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-15, Atlanta, Georgia 30341-3724.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is [http://www.cdc.gov].

CDC will not send application kits by facsimile or express mail. Please refer to Announcement Number 745 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.

Dated: May 16, 1997.

Joseph R. Carter

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

[FR Doc. 97-13429 Filed 5-21-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 752]

Health Services Research on Sexually Transmitted Diseases Prevention Within Managed Care Settings

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for applied health services research projects on sexually transmitted diseases (STDs) prevention within managed care settings.

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 Sexually Transmitted Diseases (STDs). (To order a copy of "Healthy People 2000," see the Section "WHERE TO OBTAIN ADDITIONAL INFORMATION.")

Authority

This program is authorized under Section 318 of the Public Health Service Act (42 U.S.C. 247C), as amended.

Smoke-Free Workplace

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

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit 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 or instrumentalities, federally recognized Indian tribal governments, Indian tribes

or Indian tribal organizations, small, minority, or women-owned businesses, managed care organizations and clinical public health entities such as: sexually transmitted disease (STD) clinics and family planning clinics are eligible to apply.

Applications from health departments, Indian tribal governments, academic institutions, and contractors will be required to demonstrate partnership with a managed care organization, and applications from managed care organizations will be required to demonstrate partnership with a State or local health department. All eligible applicants must have research capacity involving previous experience with health services research, and access to relevant clinic populations such as adolescents, women, minorities, and Medicaid populations.

Availability of Funds

Approximately \$650,000 is available in FY 1997 to fund up to a total of five awards in four research areas. It is expected that the average award will be \$200,000, ranging from \$100,000 to \$300,000. Specifically, organizations may submit applications in EACH or ANY of the following four research areas:

1. STD-Managed Care Prevention Services Survey. (1 year funding)
2. Quality of Service Studies. (2-3 years funding)
3. Notifiable Disease Reporting and Information Systems Studies. (2-3 years funding)
4. Population-Level STD Prevention Studies. (2-3 years funding)

It is expected that awards will begin on or about September 15, 1997, and will be made for a 12-month budget period within a one to three year project period. 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.

Use of Funds

Funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant State or local health department funds or for inpatient care, medications, or construction.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for