

pursuant to § 225.25(b)(1) of the Board's Regulation Y, and leasing real and personal property or acting as agent, broker, or adviser in leasing such property, pursuant to §§ 225.25(b)(5)(i) and 225.25(b)(5)(ii) of the Board's Regulation Y.

Comments on this application must be received by May 31, 1995.

Board of Governors of the Federal Reserve System, May 19, 1995.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 95-12845 Filed 5-24-95; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Announcement 568]

#### Community-Based Asthma Intervention Demonstration Programs

##### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for cooperative agreements for the development, implementation, and evaluation of community-based asthma intervention demonstration programs.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

##### Authority

This cooperative agreement is authorized under the Public Health Service Act, section 301 (42 U.S.C. 241).

##### Smoke-Free Workplace

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

##### Eligible Applicants

Eligible applicants are the official public health agencies of States or their

bona fide agents or instrumentalities. This 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 Palau, and federally recognized Indian tribal governments.

Only one application from an official agency (State or local) may enter the review process and be considered for award under this program. Eligible applicants may enter into contracts and consortia agreements and understandings as necessary to meet the requirements of the program and strengthen the overall application. The intent to use the above mechanisms must be stated in the application and the nature and scope of work of these mechanisms requires the approval of CDC.

##### Availability of Funds

Approximately \$200,000 will be available in FY 1995 to fund two awards. It is expected that the average award will be \$100,000. It is expected that the awards will begin on or about September 30, 1995, and will be made for a 12-month budget period within a project period of up to 2 years.

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

##### Purpose

The purpose of this project is to develop and test cost-effective, community-based asthma interventions which address one or more of the environmental risk factors among poor children. The specific objectives are:

A. Develop a community-based intervention program which is demonstrated to be cost-effective, can be sustained over time, and can serve as a model for other communities;

B. Evaluate the effectiveness of interventions which are targeted at specific risk factors;

C. Establish a network of public and private organizations and individuals within the community who share a common goal of preventing morbidity due to asthma among poor and other high-risk children to work on improved public education about asthma and its prevention and;

D. Improve the understanding concerning the prevalence of specific environmental risk factors among poor and other high-risk children with asthma.

##### Program Requirements

In conducting activities to achieve the purpose of this program, the recipient

will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities under B. (CDC Activities).

##### A. Recipient Activities:

1. Establish a mechanism for the surveillance of urgent care visits for asthma among a target population;
2. Develop a network of community organizations and individuals who share an interest in the health of poor children for the purpose of enhanced coordination of efforts aimed at patient and public education about asthma;
3. Measure the prevalence of one or more environmental risk factors within a target population and;
4. Develop, pilot test, and evaluate a community-based asthma intervention program focused primarily on one environmental risk factor.

##### B. CDC Activities:

1. Sponsor a planning workshop for all recipients and selected outside experts;
2. Collaborate with the recipient in all stages of the project, including the design of the protocol and data collection instruments, data analysis, interpretation of results, and preparation of written reports;
3. Provide on-site programmatic technical assistance in planning, implementing, and evaluating ongoing and innovative program activities;
4. Participate in improving program performance through consultation based on information and activities of other projects and;
5. Coordinate the activities of all recipients and facilitate the exchange of information and experiences among recipients.

##### Evaluation Criteria

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

##### 1. Understanding the Problem (10 points)

Evidence of the applicant's understanding of the problem and the purpose of the cooperative agreement.

##### 2. Measurable Objectives (25 points)

The consistency of the measurable objectives with the stated purpose of the cooperative agreement and the ability to meet the objectives and timetable within the specified period.

##### 3. Proposed Plan (25 points)

The adequacy of the applicant's plan to carry out the activities proposed. Of particular interest is the potential long-term sustainability of the intervention and the involvement of community organizations.

#### 4. Management and Staffing Plan (25 points)

The extent to which the proposal has described (a) the qualifications and commitment of the applicant, (b) detailed allocations of time and effort of staff devoted to the project, (c) information on how the applicant will implement and administer the project and (d) the qualifications of the key project staff.

#### 5. Proposed Evaluation Plan (15 points)

The adequacy of the applicant's plan to monitor progress toward meeting the objectives of the project.

#### 6. Budget (not scored)

The extent to which the budget is reasonable, adequately justified, and consistent with the intended use of the cooperative agreement funds.

#### 7. Human Subjects (not scored)

The applicant must clearly state whether or not human subjects will be used in research.

#### Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, Georgia 30305, no later than 60 days after the application deadline. The Announcement Number and Program Title should be referenced on the documents. The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal

governments have any tribal process recommendations on applications submitted to CDC, they should send them to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, Georgia 30305, no later than 60 days after the application deadline. The Announcement Number and Program Title should be referenced on the documents. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

#### Public Health System Reporting Requirements

This program is 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

##### *Paperwork Reduction Act*

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

##### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by appropriate institutional review committees. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

#### Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (OMB

Number 0937-0189) must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, Georgia 30305, on or before July 19, 1995.

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 objective review group. (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 shall 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 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 Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, Georgia 30305, telephone (404) 842-6634.

Programmatic technical assistance may be obtained from James Rifenburg, Air Pollution and Respiratory Health Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), Mailstop F39, 4770 Buford Highway, NE., Atlanta, Georgia 30341-3724, telephone (404) 488-7320.

Please refer to Announcement 568 when requesting information or 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 19, 1995.

**Joseph R. Carter,**

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

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**[Announcement 519]**

**Prevention of the Complications of Hemophilia**

**Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a cooperative agreement program to conduct a trial of primary prophylaxis therapy for the prevention of joint disease and/or inhibitor formation in children with hemophilia.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Diabetes and Chronic Disabling Conditions. (For ordering 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, as amended [42 U.S.C. 241(a) and 247b(k)(2)]. Applicable program regulations are found in 42 CFR Part 51b—Project Grants for Preventive Health Services.

**Smoke-Free Workplace**

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

**Eligible Applicants**

Because of the low prevalence of hemophilia, competition is limited to hemophilia treatment centers (HTCs) that routinely access and administer comprehensive health care to sufficient numbers of previously untreated patients with severe hemophilia each year. Since HTCs are the only health care facilities administering to the numbers of hemophiliacs required for this study, assistance will be provided only to hemophilia treatment centers.

**Availability of Funds**

Approximately \$500,000 is available in FY 1995 to fund up to two awards. It is expected that the award will begin on or about September 30, 1995, 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 project period will be made on the basis of satisfactory programmatic progress and the availability of funds.

**Purpose**

The purpose of this hemophilia cooperative agreement program is to assist recipients in the implementation of and analysis of data from a randomized, controlled trial of primary prophylaxis in previously untreated patients with severe hemophilia A and no demonstrable factor VIII inhibitors. Cost and efficacy of early intervention should be determined in the treatment group and should be compared to similar data from appropriately treated, control subjects. In addition to objective measures of joint function and mobility, the cumulative risk of factor VIII inhibitor development should be determined for each treatment group and total costs and complication rates ascertained. Molecular characterization of factor VIII defects and detailed molecular HLA typing should be determined for all subjects in an effort to predict which subjects will develop inhibitors.

**Program Requirements**

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

**A. Recipient Activities**

1. Develop standardized study protocols, data collection instruments, interview questionnaires, progress report forms, and amend previous protocols with new activities or procedures incorporating all changes agreed to at assistance meetings.

2. Train study coordinators and medical personnel in methods of data collection and patient assessment in the use of standard data abstraction instruments, in techniques of reviewing medical records, in interviewing patients, and in other methods of data collection as appropriate and provided for in the study protocols. It is the responsibility of the recipient to ensure uniform training of study personnel at all data collection sites and to ensure

that the data is collected in a uniform manner at all locations.

3. Develop appropriate management and evaluation systems to ensure that study personnel use data collection and interview instruments according to standard study protocols.

4. Collect and edit all data from all sites, including cost effectiveness data.

5. Obtain and transmit to CDC sufficient clinical specimens for specialized laboratory analysis and genetic testing, including whole blood, plasma, cell pellets or joint tissue/fluid, to meet the requirements of the study.

6. Publish the results of the study using a writing committee to determine the inclusion and order of authors on all publications.

**B. CDC Activities**

1. Provide consultation, and scientific and technical assistance in planning and implementing the study protocol. This assistance will include the development of standard study protocols, data abstraction instruments, interview questionnaires, consent and progress report forms.

2. Participate in the planning, coordination, and facilitation of initial and periodic meetings with recipients to exchange operational experiences, and to provide consultation and assistance in the modification of standard study protocols as needed.

3. Provide the required software and technical assistance in statistical and epidemiologic methods to conduct data analysis.

4. The coagulation research laboratory at CDC will be responsible for confirmation of factor VIII inhibitor levels and will serve as the central reference laboratory for molecular analysis of all study participants. CDC will be responsible for epitope typing of all inhibitors and other specialized immunological/genetic testing.

**Evaluation Criteria**

Applications will be reviewed and evaluated according to the following criteria: (Total 100 points)

**A. Capacity**

1. The capacity of the applicant to accrue a minimum total of 40 boys with severe factor VIII (<1%) who are 30 months old or less without a history of joint hemorrhage from multiple HTCs to each treatment arm of the protocol. Each participating HTC must be able to enroll a minimum of 5 previously untreated patients who meet the above criteria. (20 points)

2. The capacity to accrue and maintain patients on trials will be measured by (a) the number of patients