

public regarding the exclusion and detention of Japanese Americans during World War II so that the causes and circumstances of this and similar events may be illuminated and understood.

(10) Applicants are encouraged to develop a strategy and plan for reaching a broad, multicultural population through project activities.

(11) Applicants are encouraged to develop local and regional consortia of organizations and individuals engaged in similar educational, research and community development efforts.

(12) Applicants are encouraged to coordinate and collaborate with organizations and individuals engaging in similar educational, research and community development endeavors to maximize the effect of grants with respect to (a) Impact on geographic regions; and/or (b) impact on institutions, public policy, or culture; and/or (c) impact on academic field or discipline.

(13) Applicants are encouraged to utilize creative and/or innovative methods and approaches in the development and implementation of their projects.

(14) Applicants are encouraged to seek matching funds, in-kind contributions or other sources of support to enhance their proposal.

Dated: May 29, 1996.

Betty T. Sedgwick,  
*Program Analyst.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Announcement 643]

#### Cooperative Agreement To Establish Centers of Excellence To Provide Surveillance, Research, Services and Evaluation Aimed at Prevention of Birth Defects

##### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program for Centers of Excellence to provide surveillance, research, services and evaluation aimed at the prevention of birth defects. The 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. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

##### Authority

This program is authorized under sections 301 and 317C of the Public Health Service Act [42 U.S.C. 241 and 247b-4], as amended.

##### Smoke-Free Workplace

The CDC 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 State and local health departments, 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 the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments. Applicant institutions must have ongoing access to data generated from a state-based birth defects surveillance (ascertainment) program based on a population of not less than 30,000 live births per year within a State. This access will provide the source of birth defect cases for participation in the Birth Defects Risk Factor Surveillance Program (BDRFSP).<sup>1</sup> Applicants must also have a suitable source for obtaining controls from the same population from which cases are derived. State health departments or their bona fide agents must also have an ongoing surveillance program with a capability of contributing not less than a total of 400 interviews (300 cases and 100 controls) per year to the ongoing BDRFSP.

##### Availability of Funds

Approximately \$2,400,000 will be available in FY 1996 to fund three cooperative agreements (includes both direct and indirect costs). It is expected that each award will be approximately

\$800,000. It is expected that the awards will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to 5 years. The funding estimate may vary and is subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

##### Purpose

The purpose of these awards is to assist States to:

1. Bolster their ongoing surveillance activities, including the integration of prenatal diagnoses into their surveillance registry.

2. Develop, implement, and evaluate local studies chosen from among the following categories of activities:

a. Evaluation of methods for primary prevention of birth defects;

b. Evaluation of potential teratogenicity of drugs;

c. Evaluation of potential environmental causes of birth defects;

d. Evaluation of genetic susceptibilities to environmental causes of birth defects;

e. Evaluation of behavioral causes of birth defects;

f. Evaluation of costs of birth defects.

3. Contribute not less than 400 interviews per year to the BDRFSP, using the existing BDRFSP parental interview instrument.

##### Program Requirements

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

##### A. Recipient Activities

1. Develop and implement methods and approaches which will improve and expand the capacity of the applicant's existing surveillance system to ascertain cases and generate timely population-based data of birth defects including the integration of prenatal diagnoses into their registry. This may include provision of background surveillance data generated through recipient's surveillance program for collaborative efforts.

2. Develop a comprehensive plan for implementing studies that are tailored to the applicants activities, and is chosen from one of the following categories:

a. An evaluation of methods related to the primary prevention of birth defects;

b. An evaluation of the potential teratogenicity of drugs related to the possible causes of birth defects;

<sup>1</sup> See "Background" section and "Program Requirements" section of the Program Announcement included in the Application Kit for information about BDRFSP.

c. An evaluation of the potential environmental causes of birth defects; for example, endocrine disrupting chemicals or drinking water contaminants;

d. An evaluation of genetic factors influencing the occurrence of birth defects, e.g., gene—environment interactions;

e. An evaluation of the behavioral causes of birth defects;

f. An evaluation of the costs associated with birth defects.

3. Develop and implement a plan that will contribute not less than 400 interviews per year to the BDRFSP. Initially, the plan should address the development and the conduct of the BDRFSP parental interview questionnaire. This should include:

a. The development of a plan for the selection of specific cases and controls for interview;

b. The development of a plan for conducting telephone interviews of cases and controls;

c. The development of a mechanism for reducing interview data to computer readable form;

d. The conduct of parental interviews in accordance with the plans developed under activities a–c above;

e. The development of a plan to implement a more refined clinical approach to the classification of birth defects for the purpose of improving risk factor surveillance;

f. The applicant should develop a plan to implement the laboratory phase of their risk factor surveillance program, including the use of biologic specimens (to evaluate markers of exposure and susceptibility) and environmental sampling to explore the potential relationship between environmental exposures and birth defects. For example, the program may include sampling of water in the home to determine the levels of exposure to potentially harmful agents in the water.

## B. CDC Activities

### 1. Epidemiologic Research Related Activities

a. Provide consultation for the development and implementation of study protocol.

b. Assist with the review of the conduct of the study, as outlined in the protocol.

c. Provide consultation with regard to data collection and management.

d. Provide technical consultation in the review of data analysis.

e. Consult with the recipient before releasing the recipient's findings to a third party while the project is in progress.

f. Review reports of research findings being submitted for publication.

g. Provide technical assistance to project management through evaluations of the quality of performance by various program activities and staff members.

### 2. BDRFSP Related Activities

a. Assist recipients in developing a plan for the selection of specific cases and controls for interview.

b. Assist recipients in developing a plan for conducting telephone interviews of cases and controls.

c. Assist recipients in developing a mechanism for reducing interview data to computer-readable form.

d. Assist recipients to develop a plan to implement a more refined clinical approach to the classification of birth defects for the purpose of improving risk factor surveillance.

e. Assist recipients in developing a plan to implement the laboratory phase of the risk factor surveillance program.

### Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria as they relate to the applicant's response to the "PROGRAM REQUIREMENTS."

#### 1. Applicant's Understanding of the Problem (10%)

The extent to which the applicant has a clear, concise understanding of the requirements, objectives, and purpose of the grant. The extent to which the application reflects an understanding of the complexities surrounding the establishment of a Center of Excellence.

#### 2. Organizational Experience (30%)

The extent to which the applicant has the skills, experience, and access to data generated from a birth defects surveillance (ascertainment) program based on a population of not less than 30,000 live births per year. This access provides the source of birth defect cases for participation as a Center of Excellence.

#### 3. Approach and Capability (40%)

The extent to which the applicant has included a description of their approach to implementing the activities as described in the Program Requirements. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project.

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.

#### 4. Program Personnel (20%)

The adequacy of the description of present staff and capability to assemble competent and trained staff to conduct the Center for Excellence. The applicant shall identify all current and potential personnel who will be utilized to work on this grant, including qualifications and specific experience as it relates to the requirements set forth in this request.

#### 5. 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 necessary to carry out this project.

#### 6. Human Subjects Review (not scored)

Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate, and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group has concerns related to human subjects, or (4) 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.

#### Executive Order 12372

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 for 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 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 300, Mailstop E-13, Atlanta, GA 30305, no later than 45 days after the application deadline. (The appropriation for this financial assistance program was received late in the fiscal year and would not allow for an application receipt date which would accommodate the 60-day State recommendation process period.) The Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" the 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 300, Mailstop E-13, Atlanta, GA 30305, no later than 45 days after the application deadline date. The Announcement Number and Program Title should be referenced on the document. 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

##### *Human Subjects*

The proposed project involves research on human subjects, therefore, 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 the project 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 forms 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.

##### *Paperwork Reduction Act*

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

##### *Women, Racial and Ethnic Minorities*

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-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, pages 47947-47951, dated Friday, September 15, 1995.

#### Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted 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 300, Mailstop E-13, Atlanta, GA 30305, on or before August 5, 1996.

##### *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 U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

##### *2. Late Applications*

Applications which 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 David Elswick, 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 E-13, Atlanta, GA 30305, telephone (404) 842-6521, Internet address: DCE1@opspgo1.em.cdc.gov, or facsimile (fax) (404) 842-6513. Programmatic technical assistance may be obtained from Larry Edmonds, Associate Chief for State Services, or Terry G. Fitch, Public Health Advisor, Birth Defects and Genetic Diseases Branch, 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-45, Atlanta, GA 30341-3724, telephone (770) 488-7160, e-mail address: lde@cehbddd.em.cdc.gov.

Please refer to Announcement 643 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.

Atlanta, Georgia, will be the host of the 1996 Summer Olympics Games (July 19 through August 4, 1996). As a result of this event, it is likely that the Procurement and Grants Office (PGO) may experience delays in the receipt of both regular and overnight mail deliveries. Contacting PGO employees during this time frame may also be hindered due to the possible telephone disruptions.

To the extent authorized, please consider the use of voice mail, e-mail, and fax transmissions to the maximum extent practicable. Please do not fax lengthy documents, contract proposals or grant applications.

Dated: June 4, 1996.

Joseph R. Carter,

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

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#### [Announcement Number 638]

### **Development and Feasibility Testing of Interventions to Increase Health-Seeking Behaviors in, and Health Care for, Populations at High Risk for Gonorrhea**

#### **Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program to conduct research to: (a) Identify factors (at the client, provider, and systems levels) that influence the health-seeking behaviors of, and health services for, populations at high risk of transmitting and acquiring gonorrhea; (b) use the above information to develop and test interventions to increase health care seeking and improve health care; and (c) develop interdisciplinary approaches and augment a behavioral research infrastructure related to sexually transmitted diseases (STDs).

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 STDs and HIV Infection. (For ordering 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 Act [42 U.S.C. 247c], as amended.

#### **Smoke-Free Workplace**

The 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 research organizations and their agencies. Thus, universities, colleges, hospitals, research institutions and other public and private organizations and small, minority and/or women-owned businesses are eligible to apply. Also, 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 \$1 million is available in FY 1996 to fund approximately 5 awards. The project will be conducted in two stages. The project period for Stage I is expected to be two years. For Stage I, it is expected that the average award will be \$250,000, ranging from \$200,000 to \$300,000. It is expected that the awards will begin on or about September 30, 1996, and will be made for a 12-month budget period. Funding estimates may vary and are subject to change. Before completion of Stage I, recipients will compete for continuation awards for Stage II which is expected to be an additional two years. Successful completion of Stage I is required to compete for Stage II.

#### **Stage I—(Years 1 & 2)**

Focuses on formative research to identify client, provider, and system level determinants of health care seeking by, and health care for, populations at high risk of transmitting and acquiring gonorrhea.

#### **Stage II—(Years 3 & 4)**

Focuses on developing and testing the client, provider, and system level

interventions to increase health care seeking by, and to improve health care for, populations at risk for gonorrhea.

Further detail on Stages I and II is presented below under the "PURPOSE" section. Continuation awards within an approved project period will be based on satisfactory progress and the availability of funds.

#### **Purpose**

The overall purpose of this program is to assist the recipients in developing and utilizing behavioral and social science research methods to learn the influences on health care seeking and health care at the client, provider, and system levels, and to use this information to develop:

- \* Community-level behavioral interventions to increase health care seeking and;

- \* Provider and systems interventions to improve health care for populations at high risk of transmitting and acquiring gonorrhea.

The research program has two stages of activity and funding:

*Stage I: Formative Research and Intervention Development.*

*Stage II: Intervention Implementation and Feasibility Testing.*

The fundamental goal of this program announcement is best understood in the context of Stage II (years 3 and 4 of the anticipated 4-year project), in which the grantees will implement and evaluate the feasibility of a science-based community intervention to increase health care seeking among those at high risk for gonorrhea. In addition, the recipients will implement and evaluate the feasibility of science-based provider and systems interventions to improve health care for this same population. Applications for such Stage II intervention activities are not required at this time because well-developed, science-based, promising approaches to changing health-seeking behavior or the provision of health care will be based upon the aggregate results of the research conducted by grantees during Stage I.

#### **Program Requirements**

The following are applicant requirements:

(1) For research institutions, a documented research partnership with a public health agency of a State or local government or their bona fide agents. For health agencies, a documented research partnership with a university or other qualified research institution. Applicants are also encouraged to demonstrate ongoing collaboration with community-based organizations (CBOs)