Dated: May 16, 2000.

**John L. Williams,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

**[Program Announcement 00072]**

## Project CHOICES Efficacy Study; Notice of Availability of Funds

### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Project CHOICES (Changing High-risk AlcOhol Use and Increasing Contraception Effectiveness Study) Efficacy Study. The purpose of the study is to establish efficacy of Project CHOICES, a behavioral intervention approach to reducing alcohol-exposed pregnancies, in a multi-site, randomized clinical trial. Project CHOICES targets non-pregnant women at high risk for an alcohol-exposed pregnancy with a dual focused intervention aimed at reducing risk drinking and engaging in effective contraception until risk drinking is resolved. High-risk women will be accessed in high prevalence, community-based settings. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and morality and improve the quality of life.

This announcement is related to the focus areas of Substance Abuse: Alcohol and Other Drugs; and Maternal, Infant, and Child Health. For the conference copy of ''Healthy People 2010,'' visit the internet site: ≤http://www.health.gov/healthypeople>

### B. Eligible Applicants

Eligible applicants are limited to those previously funded under Program Announcement No. 746: Nova Southeastern University, The University of Texas—Houston, and Virginia Commonwealth University.

These applicants have been funded by CDC since 1997 to develop and implement the Project CHOICES Feasibility Study. This new cooperative agreement would allow the grantees to implement the study as a clinical trial.

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

### C. Availability of Funds

Approximately $900,000 is available in FY 2000 to fund approximately 3 awards. It is expected that the average award will be $300,000, ranging from $250,000 to $350,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

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

### D. Program Requirements

Project CHOICES targets non-pregnant, fertile women, 18–44 years of age, who are moderate to heavy alcohol consumers. Potentially high prevalence populations of targeted women have been defined from previous studies, including the Project CHOICES Feasibility Study which is currently underway. Applicants must select from the following list of high prevalence populations two settings in which they will conduct the Project CHOICES Efficacy Study: A jail; an alcohol and drug treatment center; an Obstetrical-Gynecological clinic; a Sexually Transmitted Disease (STD) Clinic; a media-recruited population of high-risk women; a Women, Infants, and Children (WIC) clinic; or an HMO. Applicants will then implement a behavior intervention protocol drawn from the Project CHOICES Feasibility study in two selected settings. Applicants must demonstrate the ability to maintain a minimum of 200 women from each selected setting (to be equally randomized to experimental and control groups) in the clinical study.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

*1. Recipient Activities*

a. Refine Project CHOICES protocol and implement as a clinical trial in two diverse settings.

b. Recruit and train staff in a timely manner to ensure study implementation within the 3-year project period.

c. Implement appropriate quality assurance procedures to assure that protocols for the efficacy study are being properly implemented.

d. Develop manuscripts and presentations describing the Project CHOICES Efficacy Study, results and recommendations.

*2. CDC Activities*

a. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

b. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Assist in the overall coordination of the implementation and evaluation of the intervention protocol.

d. Provide current scientific information, and ensure adherence to appropriate scientific standards including human subject regulations.

### E. Application Content

*Applications*

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 double-spaced pages (excluding attachments), printed on one side, with one inch margins, and unreduced font. Do not include any spiral or bound materials or pamphlets.

Program Narrative (not to exceed 25 pages):

The Program narrative should follow the PHS–398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. A demonstrated understanding of the problem of FAS and other prenatal alcohol-related conditions, and the role of brief intervention and treatment approaches to preventing these disorders; a justification of the need for the proposed study and the grantee's rationale for targeting the two selected settings as ones in which high prevalence populations of women at risk for a alcohol-exposed pregnancy can be accessed; and a description of how this study addresses Health People 2010 Objectives and the recommendations of the Institute of Medicine report: Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention and Treatment.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the approach to be taken in implementing

the study and the methods by which the objectives will be achieved and evaluated, including their sequence. A comprehensive evaluation plan must be outlined.

4. A description of the cooperative agreement's principal investigator's role and responsibilities.

5. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the study, as well as that portion of their salary to be paid by the cooperative agreement.

6. A description of the involvement of other entities that will relate to the proposed project, (*i.e.* recruitment settings), and letters of support as appropriate.

7. A detailed first year's budget for the cooperative agreement with future annual projections, if relevant. Awards will be made for a project period of up to three years.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use ''asterisks'' to indicate those individuals for whom salaries and fringe benefits are not shown; the salaries and fringe benefits subtotals must still be shown. In addition, the applicant must submit an additional copy of page four (Form PHS–398), completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

**F. Submission and Deadline**

*Application*

Submit the original and 5 copies of PHS 398 (OMB Number 0925–0001). Adhere to the instructions on the Errata Instruction Sheet for PHS–398. Forms are available at the following Internet address: www.cdc.gov, or in the application kit.

On or before July 17, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

*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 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 acceptable as proof of timely mailing.)

*Late Applications:* Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

**G. Evaluation Criteria**

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. *Applicant's Understanding of the Problem* (10 percent): The extent to which the applicant demonstrates an understanding of the problem of FAS and other alcohol-related birth defects, alcohol use patterns of childbearing-age women, and the maternal risk factors which contribute to harmful alcohol use during pregnancy. Also, a demonstrated understanding of the process of changing alcohol use behavior and of why pregnancy postponement is an important strategy for preventing alcohol-exposed pregnancies.

2. *Goals and Objectives* (15 percent): The extent to which the study goals are clearly stated and the objectives are specific, measurable, and time-phased. Also, the extent to which a plan is presented for evaluating the objectives.

3. *Description of the Target Population and Outline of Approach* (20 percent): The extent to which the applicant has provided a full and comprehensive description of the target population, including available statistics which provide reasonable justification for designating the group targeted as high risk for an alcohol-exposed pregnancy.

4. *Plan of Operation* (25 percent): The extent to which the applicant has provided an overall description of the approach to be taken in conducting the intervention trial. The applicant's description of its methods for alcohol assessment, counseling and referral for problem drinking, and provision of family planning services to high-risk clients. Applicant must also provide adequate demonstration of its ability to access a study population of at least 600 high-risk women annually, and to follow a cohort of 200 high-risk women for intervention activities.

Also to be evaluated under this section is 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 women 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.

5. *Capacity to Conduct Project Activities and Begin Study Operations in a Timely Fashion* (30 percent): The extent to which the applicant has provided information to support its ability to conduct the activities of the cooperative agreement including documentation of previous research experience in behavioral science research focusing on women's health issues, and/or addictive disorders; documentation of institutional support for the project; demonstrated ability to identify qualified personnel to fill key positions (including principal investigator, project coordinator, and intervention coordinator) and begin study activities in a timely fashion; and a description of how space required for the study will be acquired or designated.

6. *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.

7. *Human Subjects Review* (not scored): Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

**H. Other Requirements**

*Technical Reporting Requirements*

Provide CDC with original plus two copies of:

1. Semiannual progress reports;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 in the application kit.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

**I. Authority and Catalog of Federal Domestic Assistance Number**

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

**J. Where To Obtain Additional Information**

This and other funding opportunities may be found on the CDC home page on the Internet: http://www.cdc.gov.

To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

William Paradies, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146; Telephone number: (770) 488–2721; Email address: wep2@cdc.gov.

For program technical assistance, contact:

Dr. Louise Floyd, (770) 488–7370, Email address: rlf3@cdc.gov .

OR

Connie Granoff, (770) 488–7513, Email address: clg4@cdc.gov. Division of Birth Defects, Child Development, and Disability and Health, National Center for Environmental Health, Centers for Disease Control and Prevention 4770 Buford Highway, (F–49), Atlanta, Georgia 30341–3724.

Dated: May 16, 2000.

**John L. Williams,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Program Announcement 00094]**

### Cooperative Agreements for the Development of State-Based Birth Defects Surveillance Programs and the Use of the Surveillance Data for Public Health Programs; Notice of Availability of Funds

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for developing and improving birth defects surveillance and using surveillance data to develop birth defects prevention programs and activities to improve the access of children born with birth defects to health services and early intervention programs. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010'', a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Substance Abuse, Environmental Health, and Maternal, Infant, and Child Health. For the conference copy of ''Healthy People 2010'', visit the internet site: http://www.health.gov/healthypeople.

The purpose of the program is to support (1) the development, implementation, expansion, and evaluation of State based birth defects surveillance systems; (2) the development and implementation of State based programs to prevent birth defects; and (3) the development and implementation of activities to improve the access of children with birth defects to health services and early intervention programs.

**B. Eligible Applicants**

Applicants will be limited to those not currently involved in CDC Program Announcement 051 (Cooperative Agreements for Enhanced State-Based Birth Defects Surveillance and Use of Surveillance Data to Guide Prevention and Intervention Programs) and Program Announcement 643 (Centers of Excellence to Provide Surveillance, Research, Services, and Evaluation Aimed at Prevention of Birth Defects). See Attachment 1 for a list of the States funded under these program announcements.

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. The eligible States are: Alabama, Alaska, Arizona, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Nebraska, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Applicants may apply under one of two categories:

Category 1—States/territories/tribes with no birth defects surveillance systems; or

Category 2—States/territories/tribes with newly implemented or ongoing surveillance systems.

In the cover letter to the application, please state the category (1 or 2) for which you are applying.

**Note:** 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 is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

**C. Availability of Funds**

Approximately $800,000 is available in FY 2000 to fund approximately 3–6 awards in Category 1 and 3–6 awards in Category 2. It is expected that the average award will be $100,000, ranging from $50,000 to $150,000. The awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

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

**Use of Funds**

These awards may be used for personnel services, equipment, travel, and other costs related to project activities. Project funds may not be used