Dated: May 16, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–13430 Filed 5–21–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 746]

Preventing Alcohol-Exposed Pregnancies Among High-Risk Women in Special Settings; 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 for the identification of settings in which high proportions of childbearing-age women are at risk of an alcohol-exposed pregnancy, and for the pilot-testing of model intervention programs aimed at reducing their risk. Women at greatest risk of an alcohol-exposed pregnancy are those who are drinking at moderate to heavy levels (including binge drinking) and are planning for, or are at risk of, becoming pregnant.

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 to improve the quality of life. This announcement is related to the priority areas of Substance Abuse: Alcohol and Other Drugs, and Maternal and Infant Health. (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 Service Health 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 nonuse of all tobacco products. Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit organizations, and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, community-based organizations and other public and private organizations, State and local health departments or their bona fide agents, and small, minority- and/or women-owned non-profit businesses are eligible for these cooperative agreements. Also eligible to apply are other non-profit health, family planning, and substance abuse treatment providers, managed care organizations, and federally recognized Indian tribal governments.

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 $900,000 will be available in FY 1997 to award up to 3 cooperative agreements. It is expected that the awards will range from $250,000 to $300,000. Projects will begin on or about September 30, 1997, and will be made for a 12-month budget period within a project period of up to 3 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.

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 subtier contractors) 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).

Definitions and Background

Definitions

An *alcohol-exposed pregnancy* is one in which a woman consumes moderate to heavy amounts of alcohol, or engages in binge drinking during the pregnancy. *Moderate* amounts of alcohol are defined as 7–13 drinks per week; *heavy* amounts of alcohol are defined as 14 or more drinks per week; and *binge* drinking is defined as 5 or more drinks on any one occasion. A woman who is at *high risk* for an alcohol-exposed pregnancy is one who engages in moderate to heavy alcohol use or binge drinking, is sexually active, and is not effectively practicing contraception. A *high-risk setting* is any site in which a large proportion of the women served in the site meet the above definition of high risk.

Background

Fetal Alcohol Syndrome (FAS) is one of the leading preventable causes of birth defects and developmental disabilities in the United States. In addition to FAS, which is caused by heavy prenatal alcohol use, studies have documented more subtle growth and neurodevelopmental deficits among

children whose mothers drank at lower levels (equivalent to seven drinks per week during pregnancy). Reported prevalence rates for alcohol use by women during pregnancy include 18 percent (National Institute of Drug Abuse (NIDA)) to 20 percent (National Center for Health Statistics (NCHS)) for any reported use; 1 percent for moderate-heavy use (7 drinks per week or greater) (Behavioral Risk Factor Surveillance System (BRFSS)); and 2 percent for binge drinking (5 or more drinks on any one occasion) (BRFSS). Reported rates of alcohol use for childbearing-age women in general include 45 percent for any reported use (NCHS); 5 percent for 7 or more drinks per week (BRFSS); and 11 percent for binge drinking (BRFSS).

Important risk factors associated with heavy alcohol use among childbearing-age women include use of tobacco and other drugs, co-existing psychiatric conditions, history of sexual or physical abuse during childhood and/or adulthood, and a previous alcohol-exposed pregnancy. CDC studies have found that the strongest predictor of alcohol use during pregnancy is the level of alcohol use prior to pregnancy. Women who were drinking 9 or more drinks per week before pregnancy were 5 times more likely to drink during pregnancy than those who were drinking 2 drinks per week or less prior to pregnancy. Other CDC studies using data from the NCHS and the BRFSS have identified additional socio-demographic and maternal characteristics associated with moderate-heavy alcohol use during pregnancy. These include, but are not limited to, women who: are age 35 years and older; are members of minority race-ethnicity groups; have an annual household income of $l0,000 or less; currently smoke; or receive no prenatal health care.

Previous CDC efforts have shown that collaboration among grantees, CDC program personnel, and experts external to CDC, has been successful in developing effective interventions that address complex behaviors. An essential strategy for preventing alcohol-exposed pregnancies among women who are heavy alcohol users is referral for alcohol treatment services. However, given the high relapse rate among problem drinkers (50 percent), such efforts must be coupled with strategies which address pregnancy postponement until the risk of prenatal alcohol use can be overcome. Among women who are drinking at moderate levels, but levels that could be hazardous if pregnant, a reduction in drinking level may be possible with simple advice and counseling from a health care provider. However, among both groups of women, family planning health education and services should be provided to facilitate postponement of pregnancy until the alcohol level is reduced.

Recent research has shown that brief interventions to facilitate reduction in alcohol use which incorporate assessment, feedback, consequences of behavior and self-help materials for goal setting and behavior change can reduce problem drinking among clients in health care settings. Other successful approaches have focused on creating conditions which assist clients in reducing their ambivalence about changing a health risk behavior, which results in a stronger commitment to change.

Studies in contraceptive decision making and in the promotion of condom use in the prevention of sexually transmitted diseases have employed a cognitive model, Theory of Reasoned Action (TRA), in designing successful behavior change interventions. Knowledge gained from studies employing these and other approaches may have important implications for the design of innovative interventions for assisting childbearing-age women to avoid alcohol use during pregnancy by engaging participants in a dual program which addresses high-risk drinking and pregnancy postponement.

Purpose

The purposes of this announcement are to:

A. Identify settings which have a high proportion of women who binge drink and/or drink alcohol at moderate to heavy levels and are at risk of pregnancy.

B. Develop, implement and evaluate interventions which assist binge drinkers and/or moderate to heavy drinkers in reducing their drinking below risk levels and actively engage all clients in a plan for pregnancy postponement until risk drinking or alcohol abuse problems have been addressed.

C. Disseminate, as appropriate, generalizable interventions for the prevention of alcohol-exposed pregnancies.

Settings in which high-risk populations may be accessed include Sexually Transmitted Disease (STD) clinics, Women, Infants, and Children (WIC) clinics, mental health programs, social services settings, drug and alcohol treatment centers, and correctional systems. In addition, hospitals with high prevalence rates of prenatal alcohol use among their obstetrical populations may constitute an important setting for identifying women at high risk for an alcohol-exposed pregnancy.

The intervention to be developed will include: (1) counseling regarding the consequences of alcohol use during pregnancy; (2) brief advice and counseling for moderate to heavy drinkers to reduce intake levels or referral to treatment options in the community for alcohol-dependent drinkers; and (3) reproductive health education regarding contraceptive methods, provision of contraceptive services, and client follow-up. Interventions will be designed to be delivered to high-risk clients in the clinic or agency setting by project personnel.

Program Requirements

The applicant must:

Identify two different high-risk settings in which epidemiologic and intervention activities will be conducted. Applicants must justify their choice of each high-risk setting with prevalence rates that demonstrate problem drinking among the target population. Each setting should document an annual population of at least 500 high-risk women. The applicant must implement and evaluate model interventions for preventing alcohol-exposed pregnancies in these two settings. Intervention demonstration activities must be conducted in a cohort of 50–100 high-risk women.

An affirmative response to the above requirement is required to qualify for the full objective review. This page should be included as the first page of the application and titled ''Program Requirements.''

Cooperative Activities

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. Collaborate with other cooperative agreement recipients to:

a. Design study activities which include developing an epidemiologic survey and model interventions (including protocols) which will be implemented in the targeted populations.

b. Develop data collection instruments, study procedures, and an evaluation plan to determine the effectiveness of the interventions.

2. Implement an epidemiologic survey which characterizes the target

population in terms of the prevalence and patterns of alcohol use, prevalence of characteristics associated with heavy alcohol use, reproductive health status (e.g., parity, contraceptive practices, current sexual activity, fertility), alcohol treatment histories, and psychiatric co-morbidities.

3. Collect and analyze information that describes barriers to contraception and to alcohol abuse treatment among the target population including:

a. Knowledge, attitudes, and beliefs about alcohol use, contraception, and alcohol use during pregnancy;

b. Accessibility of services for contraception and dealing with alcohol abuse problems;

c. Peer group norms toward alcohol use and use of contraceptives; and

d. Sexual partner and family member attitudes toward contraception and alcohol use.

4. Implement a model intervention in the high-risk target sites, including quality assurance (QA) procedures to assure that protocols for piloted interventions are being properly implemented.

5. In Year 03 of the project, participate in a meeting with other funded sites to define the most promising approaches which should be incorporated into a common intervention protocol for possible testing in a randomized clinical trial.

6. Develop a manuscript describing the target populations chosen by the applicant and the results of the specific interventions tested by the individual applicant.

7. Collaborate with other funded study sites in developing a single manuscript collectively describing the various interventions piloted in the various high-risk settings by applicants funded under this cooperative agreement.

B. CDC Activities

CDC staff will collaborate with cooperative agreement recipients, providing guidance and coordination throughout the duration of the project. Activities that will be conducted by the CDC include:

1. Participate in developing protocols for the epidemiologic survey of the targeted sites and the intervention to be tested; outline data to be collected at the targeted sites; develop standardized data collection instruments and procedures; and establish a timetable for study activities.

2. Assist in the overall coordination of the development, implementation, and evaluation of the intervention.

3. Provide leadership and current scientific information on relevant intervention approaches and provide oversight of epidemiologic and intervention research design to ensure adherence to appropriate scientific standards.

4. Conduct periodic site visits to observe and discuss development and implementation of study activities.

5. Coordinate the compilation of a monograph and other documents describing interventions tested and resulting recommendations, to be distributed appropriately.

6. Maintain a multi-site data base to develop 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 grantees. 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 will be 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 first page of the application should contain the response to the Program Requirements section and be marked ''Program Requirements.''

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 follow the printed forms and precede the Program Narrative.

B. Program Narrative (Not to Exceed 25 Pages)

The Program Narrative Section should not exceed 25, double-spaced pages (excluding attachments). The program narrative should address the following:

1. Background: Briefly describe:

a. Understanding of the problem of FAS and other conditions associated with prenatal alcohol use, and why the applicant is interested in participating in a project aimed at preventing alcohol-exposed pregnancies;

b. Sociodemographic characteristics of the population of childbearing-age women targeted by the applicant including age distribution, race/ethnicity, marital status, parity, income, education, and behavioral characteristics available (e.g., smoking status);

c. Alcohol use patterns of the women in the target group including levels (e.g., moderate, heavy, and binge drinking) and patterns of use among pregnant and non-pregnant women, rates of alcoholism, rates of alcohol treatment, and any other relevant data available (i.e., alcohol-related injuries and deaths);

d. Reproductive patterns of the targeted population including number of live births per year, abortion rates, fertility rates, prenatal care rates, and contraceptive use rates;

e. Geographic area in which the clients reside (urban, rural), transportation systems available, etc.;

f. Full range of services supplied to the target population by the applicant;

g. Other general health care resources available to clients in the target population as well as specific services for alcohol treatment and family planning.

2. Organization: Briefly describe:

a. How the applicant will access women in the high-risk settings being targeted;

b. Current working relationship between the applicant and the public health department, family planning service providers, and alcohol and substance abuse treatment providers as appropriate;

c. Proposed organization structure, with lines of authority, for implementing and managing the study activities. Staff should include a

principal investigator (recommend at least 10 percent time of an individual at the doctorate level with published research to provide oversight); a project coordinator who oversees all study activities including the epidemiologic component; an intervention coordinator who assures implementation of the model intervention and oversees data collection for this component; data entry and clerical support;

d. Current working relationship with any research, academic, or scientific groups, or community-based or other affiliated organizations;

e. Strategy for recruitment of study participants in the target group;

f. Plans for conducting this study while meeting other current clinical or research commitments;

g. The degree to which human subjects may be at risk and the assurance that the project will be subject to initial and continuing review by the appropriate institution review committees;

h. The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation.

3. Capacities: Describe the capacity and experience of the applicant and the clinical/agency site(s) in which the intervention study will be conducted including:

a. Description of previous behavioral and women's health research conducted;

b. Description of the setting in which participants will be recruited into the study, and the commitment to designate office and operating space for the study;

c. Commitment to begin study implementation by January 1, 1998, including letters of commitment from study sites to begin participation by this date.

4. Current Level of Service Delivery: Provide data from the past year on the following:

a. The number of women in the high-risk target group who are seen/accessed annually by the applicant (e.g., must see at least 500 high-risk women per year in each setting);

b. Proportion of clients seen in one year who are ongoing versus new (intervention implementation requires the ability to track 50–100 high-risk women over one year);

c. Rate of return appointments versus those lost to follow-up;

d. Description of any other studies currently under way in the proposed study site.

5. Approach:

a. Describe, in summary, the approach to be taken by the applicant in implementing this cooperative agreement including identification of appropriate staff to perform essential study activities; recruitment of participants for intervention implementation; delivery of the essential components of the intervention; follow-up of clients in the intervention project; and quality assurance of quantitative data collected and protocol implementation.

b. Identification of potential problem areas in the implementation of survey and intervention activities in projected study sites.

6. Assurances: The applicant must provide the following:

a. Assurance that study documents will be handled and stored to ensure confidentiality and assure retention;

b. Assurance that project staff will be hired in a timely manner;

c. Assurance that key project personnel (or designees if the individuals filling these positions have not been employed at the time) will meet with CDC in Atlanta within 1 month of award to discuss initial study activities.

7. Budget and Line-Item Justification: This section must include a detailed first-year budget and narrative justification with future annual projections. The applicant should describe the program purpose for each budget item. For contracts contained within the application budget, applicants should name the contractor, if known; describe the services to be performed; justify the use of a third party; and provide a breakdown of and justification for the estimated costs of the contracts, the kinds of organizations or parties to be selected, the period of performance, and the method of selection.

Budget should include travel for the key study personnel to meet 3 times per year with CDC and may include incentives for subjects to maintain participation in study activities.

Review and Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and affirmative response as outlined under the previous heading, ''Program Requirements.'' Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration.

An Objective Review of applications that are successful in the preliminary review will then be conducted according to the following criteria:

A. Applicant's Understanding of the Problem (20%)

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.

B. Description of the Target Population and Outline of Approach (50%)

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, as well as an overall description of the approach to be taken in conducting the epidemiologic survey and delivering the model interventions. How the applicant will address alcohol assessment, counseling and referral for problem drinking, and provision of family planning services to high-risk clients should be clearly stated. Applicant must also provide adequate demonstration of its ability to access a study population of at least 500 high-risk women annually, and to follow a cohort of 50–100 high-risk women for intervention activities.

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 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. Capacity to Conduct Project Activities and Begin Study Operations in a Timely Fashion (30%)

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.

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 necessary to carry out this project.

E. Human Subjects 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 Review

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 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, they should reference Announcement 746 and 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 reference Announcement 746 and 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 Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(ies) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF424).

B. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not to exceed one page, and include the following:

1. A description of the target population(s) to be served;

2. A summary of primary prevention activities to be implemented and evaluated;

3. A description of the coordination plans with the community working partners for developing, implementing, and evaluating the primary prevention activities.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the SPOC or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number assigned to this program 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;

c. 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.

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).

[FR Doc. 97–13428 Filed 5–21–97; 8:45 am]

BILLING CODE 4163–18–P

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