

on smoking cessation and adoption of no smoking policies in the home.

B. Eligible Applicants

Assistance will be provided only to the University of Rhode Island. No other applications are solicited. The Conference Report H.R. 4577, Consolidated Appropriations Act, 2001, specified these funds for The University of Rhode Island to establish a program to compare media and policy interventions.

C. Availability of Funds

Approximately \$839,506 is available in FY 2001 to fund one award. It is expected that the award will begin on or about July 15, 2001, and will be made for a 12-month budget period within a one year project period. Funding estimates may change.

D. Where to Obtain Additional Information

Business management technical assistance may be obtained from: Lucy Picciolo, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01080, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone Number (770) 488-2683, Email Address: lip6@cdc.gov.

Program technical assistance may be obtained from: Corinne Husten, MD, MPH, Branch Chief, Epidemiology Branch, Office of Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Highway, NE, MS K-57, Atlanta, GA 30341, Telephone Number (770) 488-5756, Email Address: EHusten@cdc.gov.

Dated: April 17, 2001.

John L. Williams,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01074]

Intervening With Children and/or Adolescents With Fetal Alcohol Syndrome/Alcohol Related Neurodevelopmental Disorders; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for participation in a collaborative research consortium for identifying, developing, and evaluating effective strategies for Intervening with Children and/or Adolescents with Fetal Alcohol Syndrome (FAS)/Alcohol Related Neurodevelopmental Disorders (ARND). This program addresses the "Healthy People 2010" focus area(s) of Substance Abuse and Maternal, Infant, and Child Health. The purpose of the program is to conduct innovative research to identify and evaluate components of a systematic intervention approach for children and/or adolescents with FAS or ARND and their families that (1) improves developmental outcomes, (2) prevents secondary conditions, and (3) provides education and support to care givers and families.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

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 \$1,200,000 is available in FY 2001 to fund approximately 3 awards. It is expected that the average award will be \$300,000, ranging from \$250,000 to \$400,000. It is expected that the awards will begin on or about September 30, 2001, 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

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. Develop a general approach for identifying, diagnosing, evaluating, and intervening with children and/or adolescents with FAS or ARND. Applicants may target a specific age group (i.e., preschoolers or adolescents), or propose a comprehensive intervention with the capacity of serving individuals across several ages. The approach must include intervention components focusing on parent involvement in the intervention as well as parent education and advocacy training or support.

b. Develop a proposed set of diagnostic and evaluation procedures for study participants. Describe the specific set of proposed intervention components targeting core deficits (e.g., impaired social skills, social communication deficits, visual-motor impairment, behavioral issues) to intervene with the targeted population of children and/or adolescents with FAS or ARND.

c. Develop the goals and objectives of the study, the data collection instruments, study procedures, and evaluation plan to be used in determining the effectiveness of intervention components.

d. Collaborate with other grantees in identification and/or development of science-based best practices for assessment and intervention with children and/or adolescents with FAS or ARND.

e. Develop outreach and recruitment procedures for identification of affected children and/or adolescents from multiple sources to maximize the possibility of ascertaining a population-based sample. Recruit a population of at least 50 children and/or adolescents with FAS or ARND to participate in each of the intervention and comparison groups.

f. Develop research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

g. Recruit and train appropriate staff to ensure proper implementation of all aspects of the research and intervention.

h. Develop and implement a research protocol with appropriate quality assurance procedures to assure that the research and intervention activities are being properly implemented.

i. Compile and disseminate results of intervention program.

j. Collaborate with other grantees and CDC to develop education and training materials derived from the intervention and research for dissemination to a broad spectrum of potential agencies that provide services to affected individuals.

2. CDC Activities

a. Assist in the development of a research protocol for 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. Provide technical assistance, if requested, for the overall coordination as well as development of the intervention and evaluation research plans.

d. Provide technical consultation and advice on all aspects of recipient activities. Provide up-to-date, scientific information about the intervention.

e. Facilitate collaborative efforts to compile and disseminate program results through publications.

E. Application Content

a. General Instructions

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 your program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one inch margins, and un-reduced font. Do not include any spiral or bound materials or pamphlets.

b. Specific Instructions

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. Program Narrative (not to exceed 25 pages) The Program Narrative Section should address the following:

1. *Background.* Briefly describe:

a. Understanding of the problem of FAS and other conditions associated with prenatal alcohol exposure, and why the applicant is interested in participating in a project to develop and evaluate interventions for this population.

b. Understanding of the need for targeted interventions for the core deficits of children and/or adolescents with FAS or ARND and understanding of the need for individualization of interventions for affected children and/or adolescents and their families.

c. The proposed study, including purpose, objectives, and core components with justification for their inclusion.

d. Description of the challenges, barriers, and problems associated with developing and implementing an intervention for children and/or adolescents with FAS or ARND.

e. Understanding of the need to include parent involvement, parent education, and parent advocacy training or support for care givers of children and/or adolescents with FAS or ARND.

f. Demonstration of population based approach to case ascertainment including description of target population, size, age distribution, race/ethnicity, care giving arrangements (e.g., adoptive families), and other relevant sociodemographic characteristics.

g. Current patterns of service delivery to the target population, including educational placement, auxiliary services (e.g., occupational therapy, psychotherapy), family support services, and access to social services (e.g., SSI, respite).

2. *Organization.* Briefly describe:

a. How the applicant will access intervention participants.

b. How the applicant will provide the proposed diagnostic, evaluation, and intervention study components to study participants.

c. How the applicant proposes to evaluate the effectiveness of the intervention study.

d. Proposed organization structure, with lines of authority, for implementing and managing intervention and research activities. Staff should include a principal investigator (recommend at least 15 percent time of an individual with a Doctorate Degree with published research to provide oversight), a project coordinator who oversees all intervention and research activities (recommend 100 percent time of an individual with at least a Master's Degree), diagnostic persons, parent educator, intervention staff, and data/statistical expert. In addition,

specialized staff required for proposed intervention should be included as appropriate.

e. Current working relationship with research, academic, scientific, or community-based organizations with relevant expertise in delivering services to children with FAS, ARND, or other developmental disabilities.

f. Plans for conducting the intervention and research activities 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 institutional review committees.

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

3. *Capacities.* Briefly describe the capacity and experience of the applicant and the clinical/agency site(s) in which the intervention and research activities will be conducted, including:

a. Description of previous intervention and developmental research conducted.

b. Description of the setting in which participants will be recruited into the study, including provision to access potential participants from the general population in addition to clinic-based recruitment. In addition, the setting for conduct of diagnostic and evaluation procedures as well as facilities for research activities. Commitment to designate office/operating space for these activities should be described.

c. Commitment to begin intervention and research activities by January 1, 2002, including letters of commitment from study sites to begin participation by this date.

4. *Current Level of Service Delivery.* Briefly describe data from the past year on the following:

a. The number of individuals with FAS and ARND who are assessed annually by the applicant (e.g., must document a population of a least 75 to 100 children or adolescents per year). Information concerning age distribution, racial/ethnic composition, and care giving situation must be provided.

b. The proportion of clients seen in one year for initial diagnosis and evaluation versus follow-up clients previously examined.

c. Rate of return appointments in relation to rate of loss to follow-up.

d. Description of any other studies currently being conducted in the proposed study site.

5. *Approach.* Briefly describe:

a. The general approach the applicant will use to develop and implement the proposed intervention, including recruitment of participants, diagnostic and evaluation of potential participants, delivery of the essential components of the intervention, follow-up of intervention participants, and quality assurance of data collection and protocol implementation.

b. Procedures to identify, evaluate, and recruit children and/or adolescents outside clinic referred samples.

c. The area of deficit and proposed targeted interventions to be developed and/or implemented.

d. Research design to evaluate the effectiveness of the general intervention approach and targeted interventions.

e. Development or implementation of parent involvement, parent education, and parent advocacy training or support for care givers.

6. *Potential Implementation Issues.* Briefly describe:

Any foreseeable problems that might arise based on previous experience with implementation of this type of intervention or evaluation research in your selected target population, and a plan for how these problems would be dealt with.

7. *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; and

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 within 2 months of award to discuss initial collaborative activities.

8. *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 or a 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. The budget should include travel for the key study personnel to meet 3 times per year with CDC and other grantees. Incentives for study participants may be included in the budget.

F. Submission and Deadline

Letter of Intent (LOI)

A letter indicating intent to respond to this announcement should be submitted. Your letter of intent should include the following information: Name of applying organization, name of principal investigator, address, telephone number, whether a specific age group will be targeted by the proposed intervention, and a brief description of core areas to be addressed as well as the general approach to intervening in these areas. The letter of intent must be submitted on or before May 18, 2001, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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 June 20, 2001, 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 (20 percent)

The extent to which the applicant demonstrates an understanding of FAS or ARND, the need for targeted interventions for this population, and the challenges, barriers, and problems

associated with developing and implementing an intervention for this population. The applicant should also demonstrate understanding of the need for individualization of interventions for children and/or adolescents with FAS or ARND, as well as the importance of care giver education and support as necessary components to an intervention approach.

2. Description of the Intervention Target Population, Outline of General Intervention Approach, and Area(s) of Targeted Intervention (50 Percent)

The extent to which the applicant has provided a full and comprehensive description of the proposed intervention target population, including recruitment procedures and methods to achieve a generalizable sample. How the applicant will address diagnosis and initial evaluation of potential participants should be described. The general approach to intervening with children and/or adolescents with FAS or ARND should be described as should implementation or development of specific targeted areas of intervention. Methods for evaluation of the overall intervention approach and specific targeted interventions should be described.

Implementation, development, and/or enhancement of parent education (including advocacy training) should be described.

The applicant must provide adequate demonstration of its ability to access a study population of at least 50 children and/or adolescents with FAS or ARND to participate in each of the intervention and comparison groups. 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 must be demonstrated. This includes: (a) The proposed plan for the inclusion of both sexes and racial/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 intervention participants includes the process of establishing partnerships with community(ies) and recognition of mutual benefits.

3. 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

intervention and evaluation research, including documentation of previous intervention and research experience in behavioral science focusing on children and/or adolescents with FAS, ARND, and/or other developmental disabilities; documentation of institutional support for the project; demonstrated ability to identify qualified personnel to fill key positions (including principal investigator, project coordinator, intervention staff, and diagnostic staff) and begin study activities in a timely fashion; and a description of how space required for the study will be acquired or designated.

4. 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 awarded funds. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project.

5. 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. Progress reports (semi-annual);
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 I in the application kit.

- AR-1—Human Subjects Requirements
- AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7—Executive Order 12372 Review
- AR-9—Paperwork Reduction Act Requirements
- AR-10—Smoke-Free Workplace Requirements
- AR-11—Healthy People 2010
- AR-12—Lobbying Restrictions
- AR-14—Accounting System Requirements
- AR-15—Proof of Non-Profit Status

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. 241 and 247b, as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

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: Virginia Hall-Broadnax, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number (770) 488-2710, Email address vdh2@cdc.gov.

For program technical assistance, contact: Dr. Jacquelyn Bertrand, (770) 488-3529; Email address: jbertrand@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: April 17, 2001.

John L. Williams,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01076]

Notice of Availability of Funds; Programs for the Prevention of Fire Related Injuries

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement for unintentional injury intervention programs to prevent fire-related injuries. 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 area of Injury and Violence Prevention. For the conference copy of "Healthy People 2010", visit the internet site: <http://www.health.gov/healthypeople>. The purpose of this cooperative agreement is to reduce the number of residential fire-related injuries and fatalities in high risk communities.

B. Eligible Applicants

Assistance will be provided only to the official public 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.

Applicants funded under Program Announcement 98054 are eligible to apply under this Announcement as a competing continuation applicant. The proposed target areas for this Announcement must be different than those currently being funded by CDC.

Note: 2 U.S.C. section 1611 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 \$1,900,000 is available in FY 2001 to fund approximately 14 awards, ranging from \$135,000 to \$160,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month