DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee (MSHRAC): Notice of Recharter

This gives notice under the Federal Advisory Committee Act (Public Law 92–463) of October 6, 1972, that the Mine Safety and Health Research Advisory Committee, National Institute for Occupational Safety and Health, of the Department of Health and Human Services, has been rechartered for a 2-year period, through November 30, 2002.

For further information, contact Larry Grayson, Ph.D., Executive Secretary, MSHRAC, CDC, 200 Independence Avenue, SW., Room 715–H, Humphrey Building, Washington, DC 20201. Telephone 202/401–2192, fax 202/260–4464, e-mail *lhg9@cdc.gov*.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 8, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01086]

Centers of Excellence for Autism and Other Developmental Disabilities Epidemiology; 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 a cooperative agreement program for Centers of Excellence for Autism and Other Developmental Disabilities Epidemiology. This program addresses the ''Healthy People 2010'' focus area Maternal, Infant, and Child Health.

The purpose of the program is to collect and analyze epidemiologic data on the prevalence, correlates, and causes of autism and other developmental disabilities. The Centers will be part of a collaborative network investigating autism spectrum disorder (ASD) and other developmental disabilities. The Centers will conduct active population-based surveillance; multi-Center analytic case-control studies; and Center-initiated special studies (see Attachment II for Background).

B. Eligible Applicants

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.

Competition is limited to State Health Departments because they maintain public health responsibility for these health conditions, and their record systems and expertise are essential to program success. State agencies, or their bona fide agents, applying under this announcement, that are other than the official State Health Department must provide written concurrence on the application from the official State Health Department.

Only one application from each State or Territory may be submitted.

Applicants must document a study population of at least 30,000 live births per year within a State, a contiguous area of a State (such as the catchment of a local health agency), or a contiguous area comprised of a combination of States.

Applicants who are unable to document the minimum study population size based on live birth data from their State Health Department or proxy data from the US Census Bureau (based on 1999 Postcensal estimates) will be determined ineligible. The applicant should include this information as part of the abstract. If it is not included, then the application will be determined as non-responsive and returned without review.

C. Availability of Funds

Approximately $2,000,000 will be available in FY 2001 to fund approximately four awards. It is expected that the average award will be $500,000, ranging from $400,000 to $700,000. 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 five 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.

Funding Preferences

Priority consideration may be given to the establishment of Centers of Excellence in different geographic areas of the United States, its Territories, and Indian tribal governments to assure a broad geographic representation insofar as possible. This is based on legislative intent as provided in the Children's Health Act of 2000. Additional priority consideration may be given to the selection of Centers of Excellence which, as a group, provide for a diverse racial and ethnic population.

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), CDC will be responsible for the activities listed under 2. (CDC Activities). A Coordinating Committee will be established to coordinate cross-Center activities as listed under 3. (Collaborative Responsibilities).

1. Recipient Activities

A. Surveillance System

1. Develop or enhance a population-based epidemiologic surveillance system for ASD and other developmental disabilities to generate timely population-based data. Activities may include, but not be limited to, development or enhancement of surveillance case definitions, multiple source case ascertainment methods (e.g., from educational and medical sources), and data collection instruments.

2. Establish or enhance a multiple-source methodology for case ascertainment by developing collaborative relationships with appropriate professionals and organizations.

3. Develop or enhance a plan for training community service providers to improve case ascertainment.

4. Implement or enhance quality assurance procedures to ensure that study protocols are followed.

5. Develop or enhance an evaluation plan for estimating the validity and completeness of the surveillance system.

6. Develop, implement, and evaluate a plan to use surveillance data to

improve community and service provider awareness of ASD and other developmental disabilities and/or access of children with ASD and other developmental disabilities to comprehensive, community-based, family-centered care.

B. Collaborative Case-Control Study

Collaborate with other Centers funded by this announcement to design, implement, analyze, and evaluate joint case-control studies based on a pooled study data base (see 3., Collaborative Responsibilities, below). The pooled data will be used by Centers funded under this announcement to address a variety of epidemiologic research issues related to ASD and other developmental disabilities. It is anticipated that the collaborative protocol would be developed and initiated in the first year of the grant award. Each Center will be responsible independently for on-site activities, such as selection and enrollment of study subjects, implementation of the joint study protocol, quality assurance procedures, data management, and timely submission of computerized data to a central repository for inclusion in a pooled data set (see 3., Collaborative Responsibilities, below).

C. Center-Initiated Special Studies

Develop, implement, and evaluate a Center-initiated special study drawing on special strengths and expertise of Center staff. It is anticipated that development of the special study would be initiated in Year 2 of the grant award and utilize the Center's surveillance and case-control study infrastructure. The study could include, but may not be limited to, the following issues related to ASD or other developmental disabilities:

1. Evaluation of pre-, peri-, and/or postnatal risk factors, including genetic factors and environmental exposures.

2. Evaluation of natural history, including associated developmental disabilities and secondary conditions.

3. Identification of biomarkers.

4. Evaluation of economic costs.

5. Development, implementation, and evaluation of intervention programs for children with ASD and their families.

D. Disseminate Findings of the Surveillance, Collaborative Case Control, and Center-Initiated Special Studies Activities for the Professional Community and the Public to Increase Public Health Awareness

E. Coordinating Committee (CC)—Participate Fully in the Establishment and Operation of the CC, Comprised of Principle Investigators of the Centers of Excellence (see 3., Collaborative Responsibilities, below)

2. CDC Activities

A. Surveillance Activities

1. Assist recipient, as requested, in the development and implementation of surveillance activities including the development of standardized surveillance case definitions.

2. Provide current information on surveillance methods, as requested, including the identification of potential sources for surveillance.

3. Assist recipient, as requested, in the development of quality assurance procedures.

4. Provide assistance, as requested, in the development of an evaluation plan for the completeness and validity of data from the surveillance system.

5. Facilitate communication/coordination among Centers, as requested, to improve efficiency of activities and quality of surveillance data.

6. Provide technical consultation regarding data analyses as requested.

B. Collaborative Case-Control Studies

1. Assist recipients as requested in developing a plan for on-site activities, such as selection and enrollment of study subjects, implementation of the joint study protocol, quality assurance procedures, data management, and timely submission of computerized data to a central repository for inclusion in a pooled data set.

2. Obtain Center for Disease Control Institutional Review Board clearances and OMB clearance as necessary.

C. Coordinating Committee

Provide assistance as requested to the Centers in the establishment and conduct of activities carried out by the CC.

3. Collaborative Responsibilities (Coordinating Committee)

The CC will provide leadership and collaborative work to: (1) Enhance surveillance efforts across all Centers, including establishment of a multi-Center pooled data set, (2) develop a plan for the multi-Center case-control study, and (3) enhance communication and collaboration among Centers. The CC will combine the expertise and resources of the Centers to achieve a more integrated and effective program in surveillance and epidemiologic studies of ASD and other developmental disabilities. It is anticipated that critical issues for understanding the epidemiology of ASD and other developmental disabilities will be better defined through the deliberations of the CC. Periodic scientific meetings and proceedings of these meetings will be used to advance the state of knowledge in the field of ASD and developmental disabilities epidemiology. The CC may designate working groups for specific purposes, made up of staff members from the Centers. The working groups could include, but may not be limited to:

1. Surveillance work groups to establish common case definitions and surveillance data elements for a multi-Center pooled surveillance data set;

2. For the collaborative case-control study, working groups to establish (a) suitable study hypotheses, (b) case and control definitions, (c) study protocol and methodology, such as collection of biosamples, and/or (d) data collection instruments.

A plan will be developed by the CC for a Center-funded repository for the pooled surveillance and case-control study data for common use by all Centers. The CC, or a designated work group, will establish procedures for management, access and use of the repository and it's pooled data.

E. Application Content

Applicants should use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated on the criteria listed, so it is important for applicants to follow them in laying out the program plan. Forms are in the application kit.

F. Submission and Deadline

Letter of Intent

A letter of intent (LOI) is requested to enable CDC to determine the level of interest in the announcement. Include name, address, and telephone number.

The LOI is requested on or before June 11, 2001. Submit the letter of intent to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and five copies of PHS 398 (OMB Number 0925–0001) on

or before July 09, 2001, 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 Objective Review Panel. (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. Understanding the Problem (15 Points)

a. Extent to which applicant has a clear, concise understanding of the requirements and purpose of the cooperative agreement;

b. Extent to which applicant understands the issues, challenges, and barriers associated with developing and implementing population-based surveillance and epidemiologic studies for ASD and other developmental disabilities;

c. Extent to which applicant understands the issues, challenges, and barriers associated with case ascertainment for ASD; and

d. Extent to which applicant describes the need for funds to develop/enhance ASD and other developmental disability surveillance and epidemiologic studies in their State.

2. Goals and Objectives (15 Points)

a. Extent to which applicant clearly describes the short-term and long-term goals and measurable objectives of the project;

b. Extent to which applicant's goals and objectives are realistic and are consistent with the stated goals and purpose of this announcement;

c. The degree to which applicant has met the CDC policy requirements regarding the inclusion of women, ethnic and racial groups in the proposed research. This includes:

i. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

ii. The proposed justification when representation is limited or absent.

iii. A statement as to whether the design of the study is adequate to measure differences when warranted.

iv. 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.

3. Description of Program and Methodology (30 Points)

a. Extent to which applicant describes the methods they will use to (1) identify all relevant sources for surveillance case ascertainment for ASD and other developmental disabilities within the study area; (2) obtain permission to access records from relevant sources; (3) develop standard case definitions for ASD and other developmental disabilities and implement a strategy to conduct multiple-source case ascertainment; (4) train community service providers to improve case ascertainment; (5) develop and implement quality assurance procedures and an evaluation plan for the surveillance system; (6) develop and implement a plan to use surveillance data to improve public awareness of ASD and other developmental disabilities and/or access to care of affected children; and (7) develop an analytic and dissemination plan, and prepare manuscripts.

b. Extent to which applicant describes the plan for implementing the collaborative case-control study, including selection and enrollment of cases and controls from the applicant's study population.

c. Extent to which the applicant describes the objectives, based on special strengths and expertise of the applicant, for a Center-initiated special study.

4. Collaborative Efforts (15 Points)

a. Extent to which applicant demonstrates the ability to collaborate with multiple sources such as school systems, diagnostic centers, health/mental health service providers and other intervention service providers for the purpose of case ascertainment (include written assurances).

b. Extent to which applicant demonstrates their willingness to collaborate with other Centers to develop joint project efforts and carry out the joint project efforts in a manner that allows for pooling of standardized data.

c. Extent to which recipient identifies possible collaborative relationships with existing surveillance and research programs that may enhance recipients' future research activities (e.g., birth defects surveillance, NIH CPEAs, PROS).

d. Extent to which collaborative efforts with other relevant programs are documented (such as Part C, State developmental disabilities programs, genetics programs etc.)

5. Evaluation Plan (10 Points)

a. Extent to which applicant describes an evaluation plan that will monitor reliability, progress, timeliness, and completeness of the objectives and activities of the project.

b. Extent to which applicant describes a study to evaluate the completeness of ascertainment of children for the surveillance portion of the study.

6. Staffing and Management System (15 Points)

a. Extent to which key personnel have qualifications, skills and experience in epidemiologic methods, public health surveillance, data management and analysis to develop and implement surveillance and analytic studies in ASD and other developmental disabilities.

b. Extent to which applicant has the ability to manage and coordinate surveillance, research, and integration components of the project.

c. Extent to which applicant demonstrates expertise in abstracting and reviewing records.

d. Extent to which there is appropriate dedicated staff time to develop and implement the project.

e. Extent to which applicant provides an appropriate time line and includes activities and personnel responsibilities.

f. Extent to which applicant demonstrates an organizational structure (include an organizational chart) and facilities/space/equipment that are adequate to carry out the activities of the program.

7. Human Subjects Review (Not Scored)

Does the applicant adequately address the requirements of 45 CFR Part 46 for the protection of human subjects?

8. Budget (Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds. Applicants should include in their first year budget two trips to CDC, Atlanta for up to two persons and two days each trip.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports (semiannual);
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.

For descriptions of the following Other Requirements, see Attachment I.

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–22 Research Integrity

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, and Section 102 of the Children's Health Act of 2000 (Pub. L. 106–310). 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: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2721, Email: nfp6@cdc.gov.

For program technical assistance, contact: Diana Schendel, Ph.D., National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, Mail Stop F–15, Atlanta, Georgia 30341, Telephone number: 770–488–7359, Email: dcs6@cdc.gov.

Dated: May 8, 2001.

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 01095]

Building Quality Parent Components for School-Based Health Programs in Elementary and Middle Schools; 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 a cooperative agreement program for Building Quality Parent Components for School-Based Health Programs in Elementary and Middle Schools. This program addresses the ''Healthy People 2010'' focus areas of Family Planning, HIV, Nutrition and Over weight, Physical Activity and Fitness, Sexually Transmitted Disease, and Tobacco Use. A goal of this program is to eliminate health disparities among different segments of the population.

The purpose of this cooperative agreement is to develop and evaluate parent-focused intervention components to be used as a supplement for school-based sexual risk reduction and chronic disease risk factor prevention programs in elementary and middle schools. These intervention components would be designed to assist parents in reducing the risk behaviors of their children. The risk factors among young people being targeted by this program are sexual risk behaviors and chronic disease risk factors which include tobacco use, physical inactivity, poor nutrition, and being overweight or at risk of becoming overweight. Interventions will target parents (i.e., primary caregivers) of elementary or middle school students.

For the purposes of this announcement, parents are defined as primary caregivers who are biological parents or legal guardians (e.g., adoptive parent, stepparent, grandparent) of elementary and middle school students. Primary caregivers are individuals who take primary responsibility for providing care for their children. Parents (i.e., primary care-givers) are eligible for the study if their elementary or middle school children currently reside with them and if they have lived in the same residence with their elementary or middle school children for at least one year prior to the study.

Sexual risk reduction interventions are programs that show promise of success or have demonstrated evidence of efficacy in delaying initiation of sexual activity among young people, increasing condom or contraceptive use among sexually active young people, or decreasing frequency of intercourse or number of sexual partners among sexually active young people. Chronic disease risk factor prevention interventions are programs that show promise of success or have demonstrated evidence of efficacy in preventing initiation or promoting a decrease of tobacco use among young people, increasing physical activity, increasing healthy eating, or decreasing the number of children who are overweight or at risk of becoming overweight. Youth tobacco use prevention programs are included in this announcement, however, youth tobacco cessation programs are not within the scope of this announcement.

Please reference to Appendix 1 for background information relevant to this program announcement.

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, territorial, and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Successful applicants shall demonstrate a history of conducting evaluation research in partnership with interdisciplinary groups of health researchers and local racial and ethnic minority communities on applied social and behavioral science projects.

Note: Title 2 of the United States Code, Chapter 26, 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.