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Dated: July 2, 2002.

Elizabeth S. Woodruff,

*Secretary to the Board, Federal Retirement
Thrift Investment Board.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02175]

Applied Research on Antimicrobial Resistance (AR): Validation of National Committee for Clinical Laboratory Standards (NCCLS) Breakpoints for Bacterial Pathogens of Public Health Importance; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2002 funds to fund grants for Applied Research on Antimicrobial Resistance (AR): Validation of National Committee for Clinical Laboratory Standards (NCCLS) Breakpoints for Bacterial Pathogens of Public Health Importance was published in the **Federal Register** on June 4, 2002, Vol. 67, No. 107, pages 38501-38503. The notice is amended as follows: On page 38502, first column, Section E. Program Requirements, Paragraph 3, should be revised to read:

“2. For organisms for which NCCLS has yet to establish and publish a standardized susceptibility testing method, a method in line with other NCCLS methods would have to be elucidated (including the appropriate quality control organisms and the ranges of MICs or zone diameters that constituted a test that was in control). Thus, potential projects include validating existing interpretive criteria for pathogens of public health importance, developing new interpretive criteria for pathogens of public health importance using existing NCCLS methods and quality control, or developing new interpretive criteria and new antimicrobial susceptibility testing methods for pathogens of public health importance using existing NCCLS methods and quality control as a starting point for novel test development.”

Dated: June 21, 2002.

Sandra R. Manning,

*CGFM, 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 02199]

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) 2002 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 areas for 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 new Center(s) will be part of an existing collaborative network (which consist of four Centers presently) 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. Quantifiable and measurable outcomes of the cooperative agreement will be measured against the Government Performance Results Act performance goal, to find causes and risk factors for birth defects and developmental disabilities in order to develop prevention strategies.

B. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 311 and 317(C) of the Public Health Service Act, (42 U.S.C. Sections 241, 243, and 247b-4), 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.

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

To be eligible, applicants must document a study population of at least 30,000 live births per year (in order to be able to detect sufficient numbers of cases) 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, based on United States Census Data (based on 2000 census data). This information should be placed directly behind the face page of the application. Applications that fail to submit the evidence requested above will be considered non-responsive and returned without review.

Note: Title 2 of the United States Code, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Availability of Funds

Approximately \$400,000 to \$700,000 will be available in FY 2002 to fund approximately one award. The average award will be approximately \$500,000. It is expected that the award will begin on or about September 30, 2002, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may change.

It is anticipated that in FY 2003, additional approved but not funded awards may be made from this announcement, if funds become available.

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. Matching funds are not required for this program.

E. 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. 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 are not 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 regarding 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 previously funded Centers to design, implement, analyze, and evaluate joint case-control studies based on a pooled study data base.

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 Two 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 prenatal, perinatal, 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. Participate fully as a member of the coordinating committee, which is comprised of principal investigators of all funded Centers of Excellence.

2. CDC Activities:

a. Surveillance Activities.

(1) Assist recipient in the development and implementation of surveillance activities including the development of standardized surveillance case definitions.

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

(3) Assist recipient, in the development of quality assurance procedures.

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

(5) Facilitate communication/coordination among funded Centers, to improve efficiency of activities and quality of surveillance data.

(6) Provide technical consultation regarding data analyses.

b. Collaborative Case-Control Studies.

(1) Assist recipients 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 CDC Institutional Review Board (IRB) clearances and Office of Management and Budget (OMB) clearance as necessary.

F. Content of Application

Letter of Intent (LOI)

An LOI is requested for this program announcement. The LOI will not be used to eliminate potential applicants, but it will enable CDC to determine the level of interest and plan for the review more efficiently. The LOI should be no more than two, double-spaced pages, printed on one side, with one-inch margins and 12 point font. The LOI should include the following information: this program announcement number; applicant's name and address; project director's name, phone number, and e-mail address.

Applications

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 the specific information noted in laying out the program plan.

G. Submission and Deadline

Letter of Intent (LOI)

On or before July 22, 2002, submit the LOI to the official designated for programmatic technical assistance identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and two copies of PHS 398 (OMB Number 0925-0001). Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

The application must be received on or before 5 p.m. Eastern Time, August 9, 2002. Submit the application to: Technical Information Management-PA 02199, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341-4146.

Deadline: Applications shall be considered as meeting the deadline if they are received before 5 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of various identified objectives of the grant/cooperative agreement. Measures of Effectiveness must relate to the performance goals as stated in section "A. Purpose" of this announcement.

Measures must be objective/quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

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

1. 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 regarding 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.

2. 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.

3. 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:

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

(2) The proposed justification when representation is limited or absent.

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

(4) 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.

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, National Institutes of Health, Collaborative Programs of Excellence in Autism).

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

5. 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.

6. 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.

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.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Semiannual progress reports, which should include:

a. Brief project description;

b. Comparison of the actual accomplishments to the goals and objectives established for the period;

c. Data requirements that demonstrates measures of effectiveness. In the case that established goals and objectives are not accomplished, or are delayed, please discuss the reason for the goals and objectives not being accomplished, as well as the anticipated corrective action needed to achieve the goals and objectives. If there is a need to change or delete goals or objectives, please discuss and explain the reason;

d. Other pertinent information, including preliminary findings from the analysis of any available data; and

e. Financial recap of obligated dollars to date as a percentage of total available funds.

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

3. Final financial status 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.

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

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."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sheryl Heard, Grants Management Specialist, Acquisition and Assistance Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02199, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2723, email address: shl3@cdc.gov.

For program technical assistance, contact: Frank Destefano, M.D., M.P.H., National Center on Birth Defects and Development Disabilities, 4770 Buford Highway, Mail Stop F-15, Atlanta, Georgia 30341, Telephone number: 770-488-7288, email address: fxd1@cdc.gov.

Dated: June 27, 2002.

Sandra R. Manning,

CGFM, 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 02059]

Cooperative Agreement for Development of the National Violent Death Reporting System (NVDRS); Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for Development of the National Violent Death Reporting System (NVDRS). This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

The purpose of the program is to begin establishing state violent death information collection systems that will form the basis of NVDRS. The purpose of NVDRS is to generate public health surveillance information at the national, state, and local levels that is more detailed, useful, and timely than is currently available. This information will help develop, inform, and evaluate violence prevention strategies at both state and national levels. The proposed system will build upon a pilot system, the National Violent Injury Statistics System (NVISS), that has been under development since 1999. Additional information on this pilot system can be found at www.NVISS.org.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Injury Prevention and Control (NCIPC):

1. Reduce the risk of youth violence.
2. Reduce violence against women.
3. Enhance the capacity of states to implement effective rape prevention and education programs.
4. Increase external input on the research priorities, policies, and procedures related to the extramural research supported by CDC.
5. Provide online access to injury prevention data.
6. Improve the uniformity, quality, and accessibility of emergency department data for public health surveillance in several states; ultimately developing the capacity to improve data in all states through development of guidelines, recommendations, or technical assistance.

B. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) (42 U.S.C. 241(a)) of the Public Health Service Act and section 391(a) (42 U.S.C. 280(b)) of the Public Service Health Act, as amended. The catalog of Federal Domestic Assistance number is 93.136.

C. 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, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and the federally recognized Indian tribal governments. In consultation with States, assistance may be provided to political subdivisions of States.

The ability to obtain population-based information from core data sets is crucial for the successful development of the NVDRS. Eligible applicants must document through letters of support access to information on individual, identifiable decedents from all of the following data sources:

1. Death certificates.
2. Medical examiner and/or coroner records.
3. Police records (Supplemental Homicide Reports at a minimum).
4. Crime laboratory records.

The letters of support must come from the agency authorized to grant access to the specific required data. They must note the most recent year for which data are available and make a statement regarding a memorandum of agreement/ understanding that is in place between the applicant and the data agency. The memorandum of agreement must provide the applicant access to data while specifying any limitations regarding data use. A copy of the memorandum of agreement/ understanding should accompany each letter of support to confirm access.

Applicants from states that do not have centralized, statewide medical examiner/coroner or police records must obtain the letters of support from the appropriate agencies serving the three largest cities within the state.

Applications that fail to submit evidence listed above will be considered non responsive and will be returned without review.

Funding will be available to those applicants who are willing to pilot test a child fatality NVDRS module developed to collect additional data