

Late Application: Application which does not meet the criteria in (a) or (b) above is considered a late application, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

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

1. Understanding of the problem (20 percent)

The applicant's ability to demonstrate an understanding of the nature of the problem to be addressed. This specifically includes description of the public health importance of the planned activities to be undertaken, and realistic presentation of proposed objectives.

2. Technical approach (25 percent)

The extent to which the applicant's proposal addresses: (1) An overall design strategy, including measurable time lines; and (2) management analysis of the data collected.

3. Ability to carry out the project (25 percent) Degree to which the applicant provides evidence of ability to carry out the proposed project and the extent to which the applicant documents demonstrated capability to achieve the purpose of this project.

4. Personnel (20 percent)

The extent to which professional personnel involved in this project are qualified, including evidence of experience similar to this project.

5. Plans for Administration (10 percent)

Adequacy of plans for administering the project.

6. Budget (not scored)

Itemized budget for conducting the project, along with justification, is provided and is reasonable and appropriate to the described project.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semi-annual progress report;
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial status report and performance report, 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 package.

AR-7 Executive Order 12372 Review
AR-10 Smoke-Free Workplace Requirements
AR-11 Healthy People 2010
AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

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

J. Where To Obtain Additional Information

To obtain additional information, contact: Sonia Rowell, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (E-13) 2920 Brandywine Road, Room 3000 Atlanta, GA 30341 Telephone (770) 488-2724 Email address svp1@cdc.gov

For program technical assistance, contact: Patrick O. Bohan, National Center for Environmental Health, Centers for Disease Control and Prevention (F-48), 4770 Buford Highway NE, Atlanta, Georgia 30341, (770) 488-7303, E-mail address pfb3@cdc.gov.

The CDC Homepage address on the Internet is <http://www.cdc.gov>

Dated: May 3, 2000.

Henry S. Cassell III,

Acting 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 00076]

Cooperative Agreement for Early Hearing Detection and Intervention (EHDI) Tracking, Research, and Integration With Other Newborn Screening Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year 2000 funds for a cooperative agreement program to promote the implementation and integration of State-based surveillance and tracking systems for Early Hearing Detection and Intervention (EHDI) and

other disorders detected by newborn screening.

The purpose of the EHDI program includes screening newborns for hearing loss, audiologic evaluation to identify infants with hearing loss, and early intervention for children identified. This program addresses "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 Vision and Hearing. For the conference copy of "Healthy People 2010," visit the internet site: <<http://www.health.gov/healthypeople>>.

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. Only one application from each State may be submitted.

Two levels of cooperative agreements will be awarded:

Level I: Eligible applicants for Level I funding are those that do not have an established State or regional centralized EHDI surveillance and tracking program, or are in the beginning stages of establishing their program and would like to expand or improve their existing surveillance and tracking program.

Level II: Eligible applicants for Level II funding are those that have an existing State or regional centralized EHDI population-based (*i.e.*, complete geographic coverage) surveillance and tracking program that includes data on at least 75 per cent of infants from a birth population of at least 30,000 live births per year. States with fewer births may form multi-State data collection regions in order to meet the eligibility requirements; these do not have to be composed of contiguous States. Level I applicants may belong only to one multi-State regional data collection site.

Applicants from multi-State regions must provide documentation from each State of their willingness to collaborate and pool data from each site in their proposed region. One State must be identified as the designated lead on a multi-State application. The lead State must submit the application and administer the award.

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.

C. Availability of Funds

Approximately \$2,300,000 will be available in FY 2000 to fund up to 13 awards. It is expected that up to nine awards will be made to Level I applicants, ranging from \$100,000–\$150,000. It is expected that up to two awards will be made to Level II option 1 applicants and up to two awards will be made to Level II option 2 applicants. Level II awards are expected to range from \$250,000–\$350,000.

It is expected that awards will begin on or about September 1, 2000, and will be made for a 12-month budget period within a project period of up to five years, depending on availability of funds. Funding estimates may vary and are subject to change. Continuation awards within the approved project period will be made on the basis of satisfactory progress as evidenced by required reports and availability of funds.

Use of Funds

Project funds may not be used to supplant other available applicant or collaborating agency funds or to supplant State funds available for screening, diagnosis, intervention or tracking for hearing loss or other disorders detected by newborn screening. Project funds may not be used for construction, for lease or purchase of facilities or space, or for patient care.

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) either Level I or Level II). CDC will be responsible for the activities listed under 2 (CDC Activities).

1. Recipient Activities

Level I

a. Establish and implement a State or regional surveillance and data tracking system to assure minimal loss to follow-up by monitoring the status and progress of infants through the three components of the EHDI program (screening, identification, and intervention).

b. Develop standardized data collection and tracking methods (*i.e.*, linking with birth certificate files) and forms, and data analysis plan in collaboration with other recipients.

c. Collect standardized EHDI data (including the type of hearing loss and

type of intervention services) from appropriate sources, such as birthing hospitals, diagnostic centers and/or intervention programs.

d. Develop mechanisms to identify and collect standardized data on infants/children with late onset or progressive hearing loss.

e. Use State or regional EHDI data in order to obtain outcome data such as: unexpected clusters of infants with hearing loss in particular regions at particular times; unexpected differences in measure of EHDI screening performance between participating birthing hospitals; false positive rates; loss to follow-up rates.

f. Document concerns from parents and professionals about the EHDI process.

g. Collaborate with State programs such as Maternal and Child Health, Part C of the Individuals with Disabilities Education Act, private service programs, and advocacy groups to build a coordinated EHDI infrastructure.

h. Integrate with other screening programs that identify children with special health care needs such as newborn blood spot screening and birth defects surveillance.

i. Prepare and publish manuscript(s) which describes the tracking system, definitions, methodology, collaborative relationships, data collection, findings, and recommendations across sites. Collaboration with other participating sites is encouraged.

j. Develop an evaluation plan to monitor progress on activities and to assess the timeliness, completeness, and success of the project.

Level II

Level II applicants will be responsible for all required Level I activities, plus implementing either Option 1 or Option 2 below, but not both options.

Option 1. Under this option, Level II applicants will collaborate with other recipients to develop and participate in a common set of activities. Level II applicants are encouraged to develop collaborative relationships with universities. They will:

a. Share information and collaborate with other Level II recipients, and with other federal and national agencies (such as, but not limited to, Health Resources and Services Administration, National Institute on Deafness and other Communication Disorders, Directors of Speech and Hearing Programs in State Health and Welfare Agencies, Joint Committee on Infant Hearing, and advocacy groups) to develop a set of core research questions and analytic guidelines for one or more of the following areas:

- i. costs of EHDI programs,
- ii. causes and associated factors for hearing loss,
- iii. benefits of early identification and intervention for children with hearing loss,
- iv. psychological and family issues.
- b. Collaborate with other award recipients to implement a common research and analytic plan and analyze data.

c. Collaborate with other Level II award recipients in an anonymized research data set. Data analysis will be conducted at the State and federal levels with the data being maintained at the individual applicant sites.

d. Collect biological samples for children identified with hearing loss.

Option 2. Under this option, Level II applicants will be responsible for activities that build on the integration of EHDI with other newborn screening and monitoring systems. They will:

a. Collaborate with programs that perform State newborn blood spot screening to identify an annual birth cohort of infants for further monitoring. Each program will select two conditions to include in their cohort; either PKU or galactosemia as one condition, and either congenital hypothyroidism or hemoglobinopathies as the other.

b. Develop a plan that is integrated with the EHDI tracking system to determine the effectiveness of the program in identifying and tracking infants with the selected conditions.

c. Develop a plan to annually document the services received and the condition (*i.e.*, medical and developmental complications) for each affected child included in the cohorts.

d. Collaborate with other Level II/Option 2 award recipients to develop a data system for the cohorts that can be integrated with other newborn screening activities and can serve as a model for other State programs.

2. CDC Activities

a. Provide technical assistance as needed on the design, development, and evaluation methods and approaches used for State-based EHDI tracking and surveillance.

b. Provide technical assistance as needed on the development of research questions and analytic guidance;

c. Provide technical assistance as needed for the collection and analysis of data across sites.

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

E. Application Content

Use the information in the Program Requirements, Application Content,

Evaluation Criteria, and Other Requirements sections to develop the application content. Forms are in the application kit. Applications will be evaluated on the criteria listed, so it is important to follow them in describing the program plan. The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities.

The application must contain the following:

Cover Letter: A one-page cover letter should state the Level and Option for which the applicant is applying and explain how the applicant fulfills eligibility requirements.

Abstract and Table of Contents: 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 clearly state which level of activities the applicant is applying for: Level I, Level II—Option 1, or Level II—Option 2. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicant's organization structure. The abstract should precede the Program Narrative. A table of contents that provides page numbers for each of the following sections should follow the abstract (all pages must be numbered).

Budget Justification: The budget should be reasonable, clearly justified, and consistent with the intended use of the agreement funds. The applicant must include a detailed first-year budget justification with future annual projections. Budgets should include costs for travel for at least one project staff person to attend two two-day meetings. The applicant should provide a budget justification for each budget item. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection.

Narrative: The narrative should be no more than 25 double-spaced pages for Level I applicants and no more than 35 double-spaced pages for Level II applicants, printed on one side, with one inch margins, and unreduced font (12 pitch). The narrative must contain the following sections:

- a. Understanding the Problem and Current Status
- b. Goals and Objectives
- c. Description of Program and Methodology

- d. Evaluation Plan
- e. Collaborative Efforts
- f. Staffing and Management System (One-page CV or resume for each key personnel must be included in an attachment)
- g. Organizational Structure and Facilities (Must include an organizational chart)
- h. Human Subjects Review

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. The LOI should specify the level (Level I or Level II, and the option if applying for Level II funding) for which the applicant is applying. Include name, address, and telephone number. The LOI is requested on or before June 6, 2000. 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 two copies of PHS 5161-1 (OMB Number 0937-0189) on or before July 6, 2000 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%)

- a. Extent to which the applicant has a clear, concise understanding of the

requirements and purpose of the cooperative agreement;

- b. Extent to which the applicant understands the challenges, barriers, and problems associated with developing and implementing an EHDI tracking and surveillance program;

- c. Extent to which the applicant describes the need for an EHDI program in their respective State(s) or the current status of their respective State(s) existing EHDI program: Number of infants/children with hearing loss; number of infants born, number of birthing hospitals with and without UNHS programs; number of infants screened, identified and referred to intervention; protocol for screening and referral, including informed consent information; description of EHDI tracking and surveillance system (if any exists); description of other relevant tracking, surveillance systems, or registries in the State and linkages with these systems or plans to link; description of diagnostic facilities and intervention services available in the State for infants/children with hearing loss;

- d. Extent to which applicant shows willingness to integrate EHDI surveillance and tracking system with other newborn screening program activities.

2. Goals and Objectives (10%)

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

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

- c. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic and racial groups in the proposed research. This includes the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation and justification when representation is limited or absent.

3. Description of Program and Methodology (35%)

- a. Extent to which applicant describes target region and number of births/year in that region;

- b. Extent to which applicant addresses all activities of Program Requirements relevant to their chosen Level/Option;

- c. Extent to which applicant describes the methods to be used to carry out the activities and provides a time line which includes personnel and other resources to complete the project.

4. Evaluation Plan (15%)

Extent to which applicant describes an evaluation plan that will monitor progress, and assess timeliness, completeness, and success of the project;

5. Collaborative Efforts (10%)

a. Extent to which applicant describes their methods for collaboration with (and includes written assurances) from hospitals, diagnostic centers, and intervention services;

b. Extent to which collaborative efforts with other screening programs are documented;

c. (Level II only) Extent to which applicant is willing to work collaboratively with other agencies and recipients to develop multi-site research questions and analytic guidelines. If additional research questions are proposed in order to address local concerns, extent to which the applicant provides a rationale and need for choosing those questions, a clear description of the methodology to be used, the resources available or needed to carry out the project;

d. (Level II only) Extent to which applicant describes their plan for integrating the EHDI program with other screening programs such as blood spot screening and birth defect registries, (Letters of agreement and cooperation from collaborating screening programs should be included). Applicants must state their willingness to work collaboratively and to modify their projects if necessary in order to accommodate multi-site projects for the purpose of integration and standardization efforts.

6. Staffing and Management System (10%)

a. Extent to which key personnel have skills and experience to develop and implement an EHDI tracking and surveillance system;

b. Extent of the managerial ability to coordinate the tracking, surveillance, and research, and integration components of the project;

c. Extent to which expertise in abstracting screening, identification, and intervention records are demonstrated;

d. Extent to which expertise in epidemiologic methods, public health surveillance, data management and computer programming is demonstrated;

7. Organizational Structure and Facilities (5%)

Extent to which organization structure and facilities/space/equipment are

adequate to carry out the activities of the program.

8. Human Subjects Requirements (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.

9. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

H. Other Requirements

Provide CDC with the original plus two copies of:

1. Semi-annual progress reports, no more than 30 days after the end of the report period.

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

3. Final financial report and performance report, 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* Addendum 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

I. Authority and Catalog of Federal Domestic Assistance Number

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

J. Where To Obtain Additional Information

This and other documents may be downloaded through the CDC homepage on the Internet at <http://www.cdc.gov> (click on "Funding"). Refer to Program Announcement 00076 when you request information.

For business management technical assistance, contact: Mattie B. Jackson, 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: 770-488-2718, E-mail address: mij3@cdc.gov.

For program technical assistance, contact: June Holstrum, Ph.D., Early Hearing Detection and Intervention Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop F-15, Atlanta, GA 30341-3717, Telephone number: 770-488-7361, E-mail address: jholstrum@cdc.gov.

Dated: May 3, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[Program Announcement 00077]

Innovative Technology Development Grant for the Assessment of Micronutrient Status in Humans Notice of Availability of Funds**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for an innovative technology development grant program for the development of appropriate and sustainable technologies for the assessment of micronutrient status in humans. This program addresses "Healthy People 2010," a national activity to reduce morbidity and mortality and improve quality of life. This announcement is related to the focus areas of Nutrition and Overweight; Maternal, Infant, and Child Health; Diabetes; Mental Health and Mental Disorders; Immunization and Infectious Diseases. For the conference copy of "Healthy People 2010," visit the internet site: <http://www.health.gov/healthypeople>.

The purpose of the program is to stimulate the development, commercialization, and application of innovative technologies which are rugged, portable, easy to operate and