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).

[FR Doc. 00–11513 Filed 5–8–00; 8:45 am]

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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

maintain, cost effective, and sustainable. The program will assess micronutrient status in people at risk for micronutrient malnutrition living in developing countries. The program will also provide assessments of rural and inner-city populations of the developing and developed world, including domestic programs in the United States, such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Such technologies may also have applicability in clinical laboratory and medical clinic settings.

B. Eligible Applicants

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

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 $500,000 is available in FY 2000 to fund up to three awards. It is expected that the average award will be $175,000. It is expected that the awards will begin on or about September 30,2000, and will be made for a 12-month budget period within a project period of up to three 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, site visits, and the availability of funds.

D. Programmatic Interest

Programmatic interest is focused on:

1. Research and development leading to appropriate technology for assessing individual and/or population status with regard to the micronutrients of iodine, iron, vitamin A, and folic acid. The objective of the technology should be aimed at detecting or monitoring deficiencies (and/or excesses) of these micronutrients by direct or indirect measurements of the micronutrients or their metabolites in blood or urine, functional changes related to the deficiency (or excess) of the micronutrient, detection of deviations from typical individual patient characteristics (such as radiant or absorbed electromagnetic energy, expired volatile compounds, changes in visual perception, changes in neurologic function), or other approaches using technologies that range from very simple, such as dipstick or blood spot type tests, to ''smart'' biosensor or ''nano-lab'' technologies.

2. Development of the technology from research and development, through product testing, clinical evaluation, production, marketing, and technical support. Research which results ONLY in findings of academic interest with no practical application to the objectives of the grant will not be considered.

E. Application Content

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 application must be submitted unstapled and unbound.

Applications for research and development grants should include technology that:

1. Estimates the nutritional status of individuals or populations with regard to one or more of the micronutrients targeted by this program. Is accurate and traceable to an accepted accuracy base or reference standard. Is sufficiently precise and reproducible to be useful for epidemiologic purposes and/or for the management of individual cases.

2. Ability to operate under field conditions of varied temperature and humidity, is easy to operate and maintain, is economical, generates minimal disposables and/or biohazard waste, consumes minimal reagents, requires minimal training or operator expertise, and can be sustained.

3. Demonstrates portability, compact, energy efficient and, if external energy is required, is capable of operating from one or more power sources such as batteries, fuel cells, solar cells, or ''house current.''

4. Is non-invasive or minimally invasive, or requires very small amounts of blood, urine, saliva, or other accessible body fluids. If bodily fluids are required for the proposed technology, applicant must describe sample collection techniques, biohazard waste disposal, and specimen transport and storage requirements.

5. Demonstrates adequate specificity and sensitivity for the required purposes.

6. Demonstrates the capability to provide a hard copy or electronic output to document patient ID together with assayed values, if the technology used has electronic processing capability.

7. Demonstrates an understanding of the value of collaboration with other researchers, partnerships, contracts, venture capital relationships, etc., to accomplish the objectives of this project.

F. Submission and Deadline

Submit the original and five copies of PHS 398 (OMB Number 0925–0001). On or before July 10, 2000, 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 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 a Special Emphasis Panel appointed by CDC.

1. Technical Expertise and Research Capacity (30 percent)

The applicant's ability to plan, implement, and conduct a successful research and development program aimed at clinical or nutritional measurement systems including the development and validation of analytical methods and/or instruments, and the ability to guide such development efforts from concept, through bench model or demonstration-of-concept prototype, to prototype for field/clinical testing and approval, to manufacture, production, marketing, distribution and support. (If applicant does not intend to carry the project from initial development through final production and marketing, a plan for how these steps will be accomplished through partnerships, or marketing/licensing of the technology to others should be described.)

2. Technical Approach (30 percent)

a. The overall technical merit of the research plan and the soundness and scientific validity of the proposed technologies. The research plan must be thoroughly described and must include a detailed explanation of the operating principles of the technology to be developed, and the rationale for selecting the nutritional status marker to be measured.

b. The adequacy of the research plan includes the extent to which the applicant has adequately addressed all issues described and how well the evaluation plan can be used to effectively measure progress towards the stated objectives.

c. The background of the application, the critical evaluation of existing knowledge, and the specific identification of the knowledge gaps which the application intends to address.

3. Understanding the Problem (20 percent)

Applicant's understanding of the nature and difficulty of nutritional assessments, and the special challenges imposed in field settings for sample collection, storage and transport, maintenance, supply, and technical support, and sustainability.

a. The clinical, nutritional, biochemical, and practical basis for the appropriate selection of measurement parameters for the micronutrient(s) addressed by the applicant.

b. The applicant's demonstration of an awareness and understanding of strengths and weaknesses of previous work related to the proposed technology.

4. Program Personnel (10 percent)

The extent to which the application has described:

a. The qualifications and commitment of the applicant including training and experience in chemistry, biochemistry, biomedical engineering, medicine, nutrition, or other relevant scientific disciplines.

b. The qualifications of the proposed key staff.

c. Detailed allocations of time and effort of staff devoted to the project.

d. Information on how the applicant will develop, implement, evaluate progress, and administer the program.

e. 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:

(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.

5. Collaboration (5 percent)

Collaboration is encouraged to accomplish the research objectives in a timely manner. The applicant should demonstrate the ability to collaborate and/or form partnerships with appropriate research centers, manufacturers, or commercial interests to conduct the described research and development plan.

6. *Plans to Publicize the Research Effort (5 percent)*

The applicant should provide an explanation of plans to encourage the publication of the research findings or otherwise make the information available to the public as soon as is feasible within the limits of protecting proprietary interests of the developer.

7. Human Subjects Protection (Not Scored)

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

8. Budget (Not Scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of grant funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. semiannual progress reports;

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.

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–3 Animal Subjects Requirements
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 section 301(a) and 317 of the Public Health Service Act, [42 U.S.C. section 241(a) and 247(b), as amended.] The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov (click on funding). Please refer to Program Announcement Number 00077 when requesting information. To receive an application kit, call 1–888–GRANTS (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 any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Sonia V. Rowell, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2724, Email address: svp1@cdc.gov

For program technical assistance, contact: Dayton T. Miller, Ph.D., Centers for Disease Control and Prevention, 4770 Buford Highway (F–18), Atlanta, Georgia 30341, Telephone: (770) 488–4452, Email address: dtm1@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

Indian Health Service

Mental Health and Community Safety Initiative for American Indian/Alaska Native Children, Youth and Families

AGENCY: Indian Health Service.