

Dated: May 21, 1999.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 99151]

#### Notice of Availability of Funds; Innovative Technology Development Grant for the Detection and Monitoring of Diabetic Hypoglycemia by Non- or Minimally-Invasive Techniques

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for an innovative technology development grant program for the development of technology for the non-invasive or minimally-invasive detection and monitoring of diabetic hypoglycemia (low blood sugar) in children, adults, and the elderly. This program addresses the "Healthy People 2000" priority areas of Diabetes and Chronic Disabling Conditions; Maternal and Infant Health; Unintentional Injuries; and Heart Disease and Stroke. The purpose of the program is to stimulate the development, commercialization, and application of innovative technology for monitoring diabetics, especially insulin dependent diabetics, who are at risk of developing hypoglycemia, a condition which can result in reduced alertness, temporary inability to communicate, loss of consciousness, seizures, coma, injury, or death.

##### 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 \$700,000 is available in FY 1999 to fund up to three (3) awards. It is expected that the average award will be \$230,000, ranging from \$100,000 to \$700,000. It is expected that the awards will begin on or about September 30, 1999 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 and the availability of funds.

##### D. Programmatic Interests

Programmatic interest is focused on:

1. Research and development leading to an appropriate technology for detecting and/or monitoring hypoglycemia, conditions related to hypoglycemia, or indicators of pre-hypoglycemia in diabetic patients during normal daily living. The objective of the technology should be aimed at detecting or monitoring the physiologic condition of hypoglycemia (e.g. Measurement of blood glucose concentration measurement, monitoring rates of change of blood glucose concentrations, measurement of metabolic products related to diabetes, monitoring changes in bodily radiant energy, or detection of deviations from typical individual patient characteristics using "smart" biosensor technology).

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.

Proposals for research and development should address technology that is:

1. Non-intrusive to the patient's lifestyle.
2. Non- or minimally-invasive (i.e., totally external to the body or very minimal intrusion through the skin barrier).
3. Simple to operate, rugged, durable, and reliable.
4. Sensitive enough to detect or alarm a hypoglycemic condition in time for the patient or caregiver to take effective action, but not prone to excessive false alarms.
5. Capable of being attached to or placed near a sleeping infant, child, or elderly person in such a manner that

normal movements during sleep will not dislodge or deactivate the device or cause a false alarm.

6. Available at cost such that the typical diabetic patient or parent of a diabetic child can afford to purchase or lease the monitoring system.

The research and development proposed should demonstrate an understanding of the value of collaboration with other researchers, partnerships, contracts, venture capital relationships, etc., to accomplish the objectives of this project.

##### 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.

##### F. Submission and Deadline

###### Application

Submit the original and five copies of PHS 398 (OMB Number 0925-0001). On or before July 22, 1999, 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 orderly processing. (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. Evidence of Technical Expertise and Research Capacity (30%)

The applicant's ability to plan, implement, and conduct a successful research and development program aimed at clinical measurement systems including the development and validation of analytical methods and/or instruments.

## 2. Technical Approach (30%)

a. The overall technical merit of the research plan and the soundness and scientific validity of the proposed hypoglycemia detection and monitoring system. The research plan must be thoroughly described and must include a detailed explanation of the operating principles of the technology to be developed.

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

c. The background of the application, i.e., the basis for the present 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%)

a. The applicant's understanding of the requirements, objectives, and interactions required for a successful research and development program.

b. The applicant must also present evidence of understanding of the difficult analytical problem presented by the complexity of individual variability in diabetes, and the unique challenges presented for non- or minimally-invasive detection or monitoring of hypoglycemia in different patient age groups.

c. The applicant must demonstrate an awareness and understanding of strengths and weaknesses of previous work related to the proposed technology.

## 4. Program Personnel (10%)

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, diabetology, or other relevant scientific disciplines

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

c. Information on how the applicant will develop, implement and administer the program

d. The qualifications of the support staff.

## 5. Collaboration (5%)

Collaboration is encouraged to accomplish the research objectives in a timely manner. The applicant should demonstrate the ability to collaborate

with other research centers, manufacturers, or commercial interests to conduct the described research and development plan.

## 6. Plans To Publicize the Research Effort (5%)

The applicants 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)

Applications which do not adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects will be rejected.

## 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 2000
- 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 99151 when requesting information. To receive 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 any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Mattie B. Jackson, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2718, Email address: [mij3@cdc.gov](mailto:mij3@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, FAX: (770) 488-4541, EMAIL: [dtm1@cdc.gov](mailto:dtm1@cdc.gov)

or  
Gary L. Myers, Ph.D., Centers for Disease Control and Prevention, 4770 Buford Highway (F-25), Atlanta, Georgia 30341, Telephone: (770) 488-4606, FAX: (770) 488-4192, EMAIL: [glm1@cdc.gov](mailto:glm1@cdc.gov)

Dated: May 24, 1999.

**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 99106]

### Social and Environmental Interventions To Reduce HIV Incidence; Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to identify social and environmental interventions to reduce HIV incidence. This program addresses