

**Notice of Opportunity for Collaboration with the National Institute of Diabetes and
Digestive and Kidney Diseases for
Development of an Automated System for Improved Glucose Monitoring and Reporting**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health is seeking a collaborator to develop an automated system from a set of specified variables for improved blood glucose monitoring and reporting. The ultimate goal is to foster real-time, two-way communication between the patient with diabetes, and the health care team providing advice to that patient such that better glycemia control is achieved.

BACKGROUND: The NIDDK investigators have developed communication and education techniques capable of restoring excellent glycemia control to nearly all appropriately motivated patients, even those with difficult to control and long-standing diabetes.

SUMMARY: The system is expected to be used in intensive insulin therapy since normoglycemia is now proven to prevent diabetes complications and to decrease mortality. In addition to monitoring and recording functions, this system must be capable of transmitting the information to a web-based data management system available at all times to both the patient and the patient's health care provider(s). Salient characteristics of the system are as follows.

- A reliable, easy-to-use, sensitive instrument for home blood glucose testing,
- An integrated mini-computer that will perform the following functions:
 - Record the time and date that a patient checks his or her blood glucose level,
 - Record the blood glucose level,
 - Calculate, and suggest to the patient, how much (if any) additional insulin should be given if the blood glucose reading is high,
 - Ask the patient if the blood glucose measurement was before or after a meal,
 - If the answer is after a meal, prompt the patient to record how many carbohydrates were consumed and the insulin dose (and, if relevant, the insulin type) given for those carbohydrates, and
 - Be able to be down loaded to the patient's home computer.
- An integrated mini-PDA to wirelessly transmit the data contained in the meter "real time" to a password-protected web-based data management system accessible by both the patient and the patient's physician.
- Data management software that uses the transmitted data to populate an informational display.
- Software capable of triggering an alert to the patient's blood glucose care provider(s) if the blood glucose level falls into a predetermined (high or low) critical range.
- Secure areas at the web-based data management system where patients can post questions or comments for the health care team, the health care team can comment, and the questions and comments can be captured, along with other identified information such as the date and time of the posting and, preferably, the identity of the individual recording the comments.

CAPABILITY STATEMENTS: The NIDDK will use the information provided in the Collaborator Capability Statements received in response to this announcement to help in selecting a Collaborator. It is the intention of the NIDDK that qualified applicants will have the opportunity to provide information to the Selection Committee through their Capability Statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria: 1. The Statement should provide specific details of the System proposed by Collaborator. 2. The Statement should provide details concerning the expertise and experience of Collaborator that is relevant to the development of the System proposed. 3. The Statement should include a detailed plan demonstrating the ability of the Collaborator to provide and implement that which it is proposing.

TERMS: The Collaborator will be expected to execute a collaboration agreement. **NO FUNDING FROM THE GOVERNMENT IS AVAILABLE.**

DATES: Only written capability statements received by the NIDDK on or before January 31, 2006 will be considered. Applicants meeting the criteria set forth in this announcement will be notified on or about March 30, 2006.

SUBMIT CAPABILITY STATEMENTS to Rochelle S. Blaustein, J.D., Director, Technology Transfer and Development, National Institute of Diabetes and Digestive and Kidney Diseases, 9000 Rockville Pike Building 12A, Suite 3011, MSC 5632, Bethesda, MD 20892-5632, phone: (301) 451-3636, fax: (301) 402-7461, e-mail: rochelle.blaustein@nih.gov For questions concerning the System, contact David Harlan, M.D., National Institute of Diabetes and Digestive and Kidney Diseases, (301) 594-3047, e-mail: davidmh@mail.nih.gov

A formatted version of the original, unmodified Notice of Opportunity is posted at: <http://TechDev.NIDDK.NIH.GOV/glucosepub.pdf>