MSC 7934, Bethesda, MD 20892, or call non-toll-free number (301) 435–0707 or E-mail your request, including your address to : Sorlie@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received on or before July 2, 2001.

Dated: April 19, 2001.

Peter J. Savage,

Acting Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute.

[FR Doc. 01–10932 Filed 5–1–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

National Institutes of Health (NIH)

National Institutes of Health Clinical Center (NIHCC); Opportunity for Cooperative Research and Development Agreement (CRADA)

SUMMARY: The National Institutes of Health Clinical Center (NIHCC) is seeking to enter at least one Cooperative Research and Development Agreement (CRADA). The goal is to develop and implement an application specific artificial neural network based intelligent computing system for on-line and off-line quality control of a process, particularly a medical process, and especially test result production in clinical laboratory automated analyzers. The development of this technology is part of the ongoing activities of the NIHCC. The term of any CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their intent to file a formal proposal no later than June 1, 2001. Formal proposals should be submitted to this office no later than July 2, 2001. Proposals received after this date will still be considered, but only after all proposals received before this date have been considered.

ADDRESSES: Questions concerning this announcement, and all research proposals, should be submitted to Bruce D. Goldstein, Esq., Technology Transfer Branch, National Cancer Institute, National Institutes of Health, Suite 450, 6120 Executive Blvd., Rockville, MD 20852, Phone: 301–496–0477, Fax: 301–402–2117. Scientific questions should be addressed to James M. DeLeo, 6100 Executive Blvd., Suite 5C01, Rockville, MD 20852; Phone (direct): 301–496–3848; Fax: 301–496–3848; e-mail: *jdeleo@nih.gov.* Inquiries directed to obtaining patent license(s) related to participation in the CRADA opportunity should be addressed to Dale Berkley, PhD., J.D., Senior Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852–3804, Phone: 301–496–7735, Fax: 301–402–0220, e-mail: *Berkld@od.nih.gov.*

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NIHCC and a collaborator pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710 a), as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. THE NIHCC IS PROHIBITED FROM TRANSFERRING FUNDS TO A CRADA COLLABORATOR. Under a CRADA, the NIHCC can offer the selected collaborator access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise, and funding to the collaboration. A CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual patent rights arising under the CRADA, and may qualify as an inventor or co-inventor of new technology developed under the CRADA. As between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NIHCC, as specified in 15 U.S.C. § 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree to manufacture CRADA products in the U.S.

The CRADA will employ a generalized computational system and method developed earlier at the National Institutes of Health. This technology was developed for the purpose of detecting errors in processes including, but not limited to, data collection in laboratory automated analyzers. The technology is capable of early on-line detection of various types of errors such as bias, precision, and random errors. It may also be developed as an off-line computational component. Theoretical studies have demonstrated significant advantages of this technology over current state-of-the art quality control practice in laboratory instrument quality control monitoring. The primary goal of the CRADA is to use the developed system and method to build practical and useful software and/or hardware components for application in real-world production or assembly process environments such as commercially available laboratory automated analyzers and other appropriate medical or non-medical applications.

The described methods and system are the subject of a U.S. patent application filed November 26, 1998 by the Public Health Service on behalf of the Federal Government. Commercialization of new CRADA technology may require obtaining an appropriate PHS license.

The collaborator in this endeavor is expected to commit technical personnel commensurate with the level of research activities defined by the CRADA Research Plan. It is anticipated that PHS facilities and/or those of the collaborator will be utilized, as appropriate, for the research activities as defined by the Research Plan. NIHCC anticipates, in addition, that the Collaborator, as appropriate, will provide funding for the project.

Party Contributions

The NIHCC anticipates that its role may include, but not be limited to, the following:

(1) Plan research studies, interpret research results, and, as appropriate, jointly publish the conclusions with the collaborator;

(2) Provide collaborator with access to existing NIHCC research data, both already collected and yet to be collected (except for medical or other personal data regarding identifiable patients);

(3) Provide staff, expertise, and materials for the development and testing of promising application products;

(4) Provide work space and equipment for testing of any prototype products developed.

The NIHCC anticipates that the role of the successful collaborator will include at least the following:

(1) Provide significant intellectual, scientific, and technical expertise in the development of relevant products;

(2) Plan research studies, interpret research results, and, as appropriate, jointly publish the conclusions; and

(3) Provide NIHCC a supply of necessary materials, access to necessary proprietary technology and/or data, and as necessary for the project, staff and funding in support of the research goals.

Other contributions may be necessary for particular proposals.

Selection Criteria

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Expertise:

A. Expertise in the research and development of diagnostic, prognostic,

and/or therapeutic products pertinent to the technology; and

B. Ability to secure national marketing and distribution of its products (international distribution a plus).

(2) Reliability as a research partner, specifically:

A. Willingness to commit best effort and to provide adequate and sustained resources and/or funding, as appropriate, to support the CRADA studies;

B. Development of this technology, as outlined in the CRADA Collaborator's proposal;

C. Ability to develop and produce products in a timely manner, as applicable (for example, as demonstrated by a history of meeting benchmarks in licenses);

D. Commitment to supporting the advancement of scientific research, as evidenced by a willingness to jointly publish research results in a prompt manner; and

E. Willingness to be bound by DHHS and PHS policies regarding:

(i) the public distribution of research tools,

(ii) the care and handling of animals, and

(iii) protection of humans who are subjects of research.

(3) Physical Resources:

A. An established headquarters, with office space and basic office equipment;

B. Access to the organization during business hours by telephone, facsimile, courier, U.S. Post, e-mail, the World-Wide-Web, and, as appropriate, other evolving information technologies; and

C. Sufficient financial and material resources to support, at a minimum, the anticipated activities of the CRADA to meet the needs of NIHCC under the proposal.

The collaborator is encouraged to propose, in the written research statement, related applications and technologies other than those specifically described herein.

Dated: April 23, 2001.

Kathleen Sybert,

Chief, TTB/NCI/NIH.

[FR Doc. 01–10933 Filed 5–1–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

National Institutes of Health (NIH)

National Institutes of Health Clinical Center (NIHCC) Opportunity for Cooperative Research and Development Agreement (CRADA)

SUMMARY: The National Institutes of Health Clinical Center (NIHCC) is seeking to enter at least one Cooperative Research and Development Agreement (CRADA). The goal is to develop and implement application specific computer-learned medical-outcome indexes as partially described in the April 2001 issue of the periodical entitled ''Advance for Administrators of the Laboratory.'' The development of this technology is part of the ongoing activities of the NIHCC. The term of any CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their intent to file a formal proposal no later June 1, 2001. Formal proposals should be submitted to this office no later than July 2, 2001. Proposals received after this date will still be considered, but only after all proposals received before this date have been considered.

ADDRESSES: Questions concerning this announcement, and all research proposals, should be submitted to Bruce D. Goldstein, Esq., Technology Transfer Branch, National Cancer Institute, National Institutes of Health, Suite 450, 6120 Executive Blvd., Rockville, MD 20852, Phone: 301–496–0477, Fax: 301–402–2117. Scientific questions should be addressed to James M. DeLeo, 6100 Executive Blvd., Suite 5C01, Rockville, MD 20852; Phone (direct): 301–496–3848; Fax: 301–496–3848; e-mail: *jdeleo@nih.gov.* Inquiries directed to obtaining patent license(s) related to participation in the CRADA opportunity should be addressed to Dale Berkley, PhD., J.D., Senior Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852–3804, Phone: 301–496–7735, Fax: 301–402–0220, e-mail: *Berkld@od.nih.gov.*

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NIHCC and a collaborator pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710 a), as amended. A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. THE NIHCC IS PROHIBITED FROM TRANSFERRING FUNDS TO A CRADA COLLABORATOR. Under a CRADA, the NIHCC can offer the selected collaborator access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise, and funding to the collaboration. A CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual patent rights arising under the CRADA, and may qualify as an inventor or co-inventor of new technology developed under the CRADA. As between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NIHCC, as specified in 15 U.S.C. 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree to manufacture CRADA products in the U.S.

As used here, the expression ''computer-learned medical outcome indexes'' refers to probability or degree of membership values indicating (''indexing'') particular medical outcomes such as diagnostic categories, preferred treatments, times to events, and other medical classifications and outcomes. These indexes and their confidence intervals are computed using laboratory and other patient data with neural networks and other machine-learning computer programs which, once trained, may run as background tasks in laboratory instrument computers, hospital information systems, and various personnel computers including desk, lap, and palm top computers. These programs could also be inscribed in hardware. It is expected that medical index computer programs will provide valuable patient information at virtually no extra cost, and that they will be in everyday use in future clinical settings to aid health care providers in making important cost-effective patient management decisions.

The described methods are the subject of an Employee Invention Report filed with the NIH Office of Technology Transfer. Also the initial report and characterization of the invention is partially described in an article entitled ''Computer-Learned Medical Outcome Indexes, by Jim DeLeo,'' in the April 2001 issue of Advance for Administrators of the Laboratory. Commercialization of new CRADA technology may require obtaining an appropriate PHS license to practice this described prior art.

The collaborator in this endeavor is expected to commit technical personnel