DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Clinical, Laboratory, and Epidemiologic Characterization of Individuals at High Risk of Cancer

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 16, 1996, pages 66052–66053 and allowed 60 days for public comment. Only one comment from the public was received; it was a request for additional information about the project. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION:

Title: Clinical, Laboratory, and Epidemiologic Characterization of Individuals at High Risk of Cancer. *Type of Information Collection Request:* Extension of OMB No. 0925–0194 (Expiration date 04/30/97). *Need and Use of Information Collection:* This ongoing research study will identify cancer-prone persons in order to learn about cancer risk and cancer causes in individuals and families. The primary objectives of this research study are to utilize clinical, laboratory, and epidemiologic approaches in studies of individuals and families at high risk of cancer to identify and further characterize cancer susceptibility factors. Respondents are members of families in which multiple cancers are thought to have occurred. Information about the occurrence of cancer is collected and reviewed to determine eligibility for further etiologic study. Participation is entirely voluntary. The findings will lead to a better understanding of the causes and risk factors for selected cancers, which may reduce cancer incidence, and promote the earlier diagnosis of some cancers. *Frequency of Response:* One time. *Affected Public:* Individuals or households. *Type of Respondents:* Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 600 per year; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .75; and *Estimated Total Annual Burden Hours Requested:* 450. The annualized cost to respondents is estimated at $4,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Margaret Tucker, Chief, Genetic Epidemiology Branch, National Cancer Institute, NIH, Executive Plaza North, Room 439, 6130 Executive Blvd., Bethesda, MD 20892, or call non-toll-free number (301) 496–4375, or E-mail your request, including your address to: tuckerp@epndce.nci.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before May 12, 1997.

Dated: April 1, 1997.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–9240 Filed 4–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

National Institutes of Health (NIH)

National Library of Medicine (NLM); Opportunity for a Cooperative Research and Development Agreement for Research and Development of Data Mining, Data Warehousing and Visualization Techniques to Commercial Products

AGENCY: Lister Hill National Center for Biomedical Communications, NLM, NIH, DHHS.

ACTION: Advertisement.

SUMMARY: The Lister Hill National Center for Biomedical Communications (LHNCBC), an R&D division of the National Library of Medicine, seeks a Cooperative Research and Development Agreement (CRADA) with a software company with a reputation in the software engineering research and development and marketing communities as demonstrated by the quality of its information products and successful application of sophisticated statistical or machine learning methods to commercial products. Of particular interest is application of data mining, data warehousing and visualization techniques to areas of interest including drug design, medical care, fraud detection, and medical administration.

The Collaborator must be able to collaborate with NLM staff to produce high quality information products. The Collaborator must have a demonstrated record of success in privately producing and marketing information resources.

The term of the CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal no later than June 9, 1997, and then will have an additional thirty (30) days to submit a formal proposal.

ADDRESSES: Inquires and proposals regarding this opportunity should be addressed to Jeremy A. Cubert, M.S., J.D. (Tel. #301–496–0477, FAX #301–402–2117), Office of Technology Development, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries regarding obtaining patent license(s) needed for participation in the CRADA opportunity may be addressed to John Fahner-Vihtelic, Office of Technology Transfer, National Institute of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, Phone: (301) 496–7735 (ext. 285); FAX: (301) 402–0220.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be

entered into by LHNCBC pursuant to the Federal Technology Transfer Act of 1986, as amended by the National Technology Transfer Act (Pub. L. 104–113 (1996)) and by Executive Order 12591 of April 10, 1987. The Computer Science Branch, LHNCBC, NLM is presently developing a system to automate key decisions in the design and execution of machine learning applications. The system, termed ''cultural coevolution'' (COEV), uses object oriented intelligent agent techniques to synergistically integrate many different machine learning approaches into a single framework. The described methods are the subject of a provisional patent application (60/018,191) filed by the Government.

Under the present proposal, the goal of the CRADA will be the development of the following parameters:

- Improved speed of the algorithm;
- Improved portability of the system;
- Integration of ''data warehousing'' functions to enable compatibility with a wide variety of database formats, remedy gaps or errors in the data (''data cleaning'') and to identify target concepts for learning;
- Development of a user interface to enable system set up and configuration, monitor algorithm progression, adjust the algorithm as necessary, and display the results in a comprehensive and useful format.

Party Contributions

The role of the LHNCBC includes the following:

(1) Provide Collaborator with COEV system information necessary for the further development of the COEV system;

(2) Provide staff, expertise, and materials for the further development of the COEV system;

(3) Evaluate the work product of Collaborator to ensure progress toward meeting the CRADA goals; and

(4) Provide work space and equipment for production and testing of any components or improvements of the COEV system.

The role of the successful Collaborator will include the following:

(1) Provide funding, if and as necessary, in support of the development of the COEV system;

(2) Provide expertise and assistance in the production and marketing of any products resulting from this CRADA;

(3) Provide staff, expertise, and materials for the development of the COEV system under this CRADA; and

(4) Provide quality assurance testing, operator training, and user support for any products resulting from this CRADA.

Selection Criteria

Proposals submitted for consideration should fully address each of the following qualifications:

(1) Expertise

A. Demonstrated expertise in translating sophisticated statistical or machine learning methods to successful products;

B. Demonstrated expertise in software engineering, data warehousing, data visualization;

C. Demonstrated ability to secure national and international marketing and distribution of software;

D. Demonstrated expertise in overseeing all aspects of product development;

E. Demonstrated intellectual ability to guide development of product line which addresses the requirement of LHNCBC;

F. Demonstrated expertise in serving and supporting a significant client base; and

G. Familiarity with application of data mining techniques to biomedical fields.

(2) Reputation

The successful Collaborator must be recognized in the software industry for:

A. Producing, marketing and supporting data mining and related applications;

B. Indications of high levels of satisfaction by software experts and users of data mining products and;

C. The range of products and services it produces.

(3) Physical Resources

A. An established headquarters with offices, space, and equipment;

B. Access to the organization during business hours by telephone, mail, e-mail, the Internet, and other evolving technologies; and

C. Sufficient financial and technological resources to support, at a minimum, the current activities of the CRADA to meet the needs of LHNCBC.

Dated: April 1, 1997.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 97–9238 Filed 4–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Opportunity for a Clinical Trial-Cooperative Research and Development Agreement (CT–CRADA) for Phase II Clinical Trial on the Use of Minocycline to Treat Osteoporosis

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Aging (NIA) is seeking a Collaborator to participate in a CT–CRADA to run a Phase II clinical trial on the use of minocycline to treat osteoporosis, and to assist in the development of analogues to minocycline.

The term of the CT–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 9, 1997. Formal proposals must be submitted to this office no later than July 9, 1997.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Bruce D. Goldstein, J.D.; Office of Technology Development, National Cancer Institute; Executive Plaza South, Suite 450; 6120 Executive Blvd., MSC 7182, Bethesda, Maryland, 20892 (Telephone No. 301–496–0477; FAX No. 301–402–2117).

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NIA pursuant to the Federal Technology Transfer Act of 1986, as amended by the National Technology Transfer Act (Pub. L. 104–113 (Mar. 7, 1996)) and by Executive Order 12591 of April 10, 1987. NIA has recently published a discovery by its staff that minocycline, an antibiotic related to tetracycline, increases bone mineral density, improves bone strength and formation, and slows bone resorption in old laboratory animals with surgically-induced menopause. Bone, 19:637–644 (Dec. 1996). Accordingly, NIA has begun to organize Phase II clinical trials.

Under the present proposal, the specific goals of the CT–CRADA will be the development of the following technology:

- Development of one or more protocols for the clinical trial of minocycline in the treatment of osteoporosis;
- Execution of clinical trials;
- Joint publication of research results; and