

utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Request:*

Extension of a currently approved collection; *Title of Information Collection:* Medicare+Choice (M+C) Provider Sponsored Organization (PSO) Waiver Request Form and Supporting Regulations in 42 CFR 422.370–422.378; *Form Number:* HCFA–R–231 (0938–0722); *Use:* The PSO waiver request form is for use by PSO's that do not have a State risk-bearing entity licence and that wish to enter into a M+C contract with HCFA to provide prepaid health care services to eligible Medicare beneficiaries. HCFA will use the information requested on this form to determine whether the applicant is eligible for a waiver of the state licensure requirement for M+C organizations as allowed under section 1855(a)(2) of the Social Security Act.; *Frequency:* One-time.; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal Government.; *Annual Number of Respondents:* 10.; *Total Annual Responses:* 10.; *Total Annual Hours Requested:* 100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA

document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, HCFA–R–231, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 23, 2001.

**John P. Burke, III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01–10882 Filed 5–1–01; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute: Proposed Collection; Comment Request; The Framingham Study

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National

Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (MB) for review and approval.

*Proposed Collection: Title:* The Framingham Study. *Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925–0216). *Need and Use of Information Collection:* The Framingham Study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third generation participants for the purpose of studying the determinants of cardiovascular disease. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows; *Estimated Number of Respondents:* 2,833; *Estimated Number of Responses per Respondent:* 3.78; *Average Burden Hours Per Response:* 0.806; and *Estimated Total Annual Burden Hours Requested:* 8,639. The annualized cost to respondents is estimated at \$44,080, assuming respondents time at the rate of \$10 per hour for participant and \$55 per hour for physicians and other professional health care respondents.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

### ESTIMATE OF ANNUAL HOUR BURDEN

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Participant examination .....	2,133	4.69	0.836	8,376.5
<sup>1</sup> Physician, hospital, nursing home staff .....	350	1.0	0.6700	234.5
<sup>1</sup> Participant's next-of-kin .....	350	1.0	0.0800	28
Total .....	2,833	3.78	0.806	8639

<sup>1</sup> Annual burden is placed on doctors, hospitals, nursing homes, and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

### 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.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Paul Sorlie, Project Officer, NIH, NHLBI, 6701 Rockledge Drive,

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](mailto: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](mailto: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,