is estimated using a rate of $10.00 per hour. The annualized cost to respondents is estimated at: $23,820. There are no Capital Costs. There are no Operating and 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 functions of the agency, including whether the information shall 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 Ms. Suzanne Anthony, Project Clearance Liaison, National Heart, Lung, and Blood Institute, NIH, Building 31, Room 5A10, MSC 2490, 31 Center Drive, Bethesda, MD 20892–2490 or call non-toll free number (301) 496–9737, or e-mail your request or comments, including your address, to: AnthonyS@gwgate.nhlbi.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before January 28, 1998.

Dated: December 17, 1997.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 97–33744 Filed 12–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Submission for OMB Review; Comment Request, National Donor Research and Education Study–II

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 (OMB) for review and approval. This proposed information collection was previously published in Volume 62, Number 86 of the **Federal Register** on May 5, 1997 (page 24,492) and allowed 60 days for public comment. One comment was received. An individual requested a summary of the study protocol, which was provided to them. 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: National Donor Research and Education Study–II. *Type of Information Collection Request:* Reinstatement with changes to OMB #0925–0383, Expiration date: 1/31/96. *Need and Use of Information Collection:* This study is the second large anonymous mail survey to be sent to a random sample of blood donors at five blood centers participating in the Retrovirus Epidemiology Donor Study (REDS). In addition to the REDS blood centers, this survey will also be sent to a sample of donors in selected non-REDS regions that utilize a variety of donor incentives. Study results will provide data for monitoring the safety of the U.S. blood supply, and will facilitate the development, evaluation and refinement of educational, recruitment and qualification strategies for U.S. blood donors. The proposed new study will update and extend the unique findings obtained in the first blood donor survey so as to minimize the likelihood that donors with risk factors for transfusion-transmitted diseases will enter the blood donor pool. There is a strong likelihood that, like the first survey effort, the resulting findings will be directly applied to blood banking operational practice. The new survey is specifically designed to obtain data on the prevalence and impact of donor incentives on donor retention and blood safety. The FDA has identified this as a priority area for investigation. Other specific objectives of this survey are to: (1) Evaluate donor understanding and acceptance, and the safety impact of newly-changed laboratory and donor screening procedures that have been implemented since the previous donor survey study (e.g., removal of the confidential unit exclusion ''CUE'' process at two REDS sites; additional questions about Creutzfeldt-jakob and parasitic diseases; and addition of HIV p24 antigen testing); (2) Estimate the efficacy, safety impact and donor acceptance of new donor screening procedures that are anticipated to occur within the next 12–24 months (e.g., improved CUE procedures, implementation of computer-assisted donor screening); (3) Provide ''pre-'' (baseline) and ''post-'' (evaluation) measures for new donor qualification procedures expected to occur operationally at blood centers within the time period of study including: deferral for intranasal cocaine use in the past year; modification of the time period for sexual risk deferrals from ''since 1977'' to within the past (12 or 24) months; clarification of wording regarding sexual contact with ''at-risk'' individuals; and addition of questions about donating primarily for the purpose of receiving the test results for the AIDS virus; (4) Assess changes in the prevalence and characteristics of donors who report donating for therapeutic reasons (e.g., those with iron storage disease), and donors who report donating primarily to receive test results for the AIDS virus as a result of the March 1996 implementation of HIV p24 antigen testing; (5) Determine the extent to which active donors with reactive tests for anti-HBc and syphilis have increased levels of behavioral risks that should have resulted in deferral; (6) Measure the extent to which seropositivity for current syphilis screening tests predicts a recent history of diagnosed syphilis; (7) Measure blood donor knowledge of infectious disease risks and the behavioral factors that should defer them from donating, to identify weaknesses in the current donor educational process, and (8) Assess the attitudes of donors regarding establishment of stored frozen repositories from their donations, use of these samples for future research testing designed to improve transfusion safety, and the adequacy of different levels of

informed consent. *Frequency of Response:* One-time data collection.
Affected Public: Individuals.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per responses	Estimated total annual burden hours requested
Blood Donors	78,000	1	.3333	25,997

The annualized cost to respondents is estimated at: $259,974 (based on $10 per hour). 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, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or obtain a copy of the data collection plans and instruments contact: Dr. George J. Nemo, Group Leader, Transfusion Medicine, Scientific Research Group, Division of Blood Diseases and Resources, NHLBI, NIH, Two Rockledge Centre, Suite 10042, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call non-toll free number (301) 435–0075 or e-mail your request, including your address to: nemog@gwgate.nhlbi.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before January 28, 1998.

Dated: December 17, 1997.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 97–33745 Filed 12–24–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cooperative Research and Development Agreement (CRADA) Opportunity and/or Licensing Opportunity for Materials and Methods for Protection of Tissue From Ischemic Damage

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking CRADA partners and/or licensees for the further development, evaluation, and commercialization of materials and methods for protecting tissues from cell injury by Ischemia. The invention claimed in U.S. Patent Application Serial No. 60/053,843, ''12(S)=HpETE (A 12=Lipoxygenase Metabolite) Significantly Reduces Cell Injury,'' is available for licensing (in accordance with 35 U.S.C. 207 and 37 CFR Part 404) and/or further development under one or more CRADAs in several clinically important applications as described below in the **SUPPLEMENTARY INFORMATION**.

DATES: CRADA proposals should be received on or before March 30, 1998 for priority consideration. However, CRADA proposals submitted thereafter will be considered until a suitable CRADA Collaborator is selected.

ADDRESSES: CRADA proposals and questions should be addressed to Dr. Jonathan Gottlieb, National Heart, Lung, and Blood Institute, Technology Transfer Service Center, 31 Center Drive MSC 2490, Room 1B32, Bethesda, Maryland 20892–2490; Telephone: 301/402–5579; Fax: 301/594–3080; E-mail: GottlieJ@gwgate.nhlbi.nih.gov.

Questions about the licensing opportunity should be addressed to Carol Lavrich, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone 301/496–7735 ext. 287; Fax 301/402–0220; E-mail: Carol—Lavrich@nih.gov.

SUPPLEMENTARY INFORMATION: Ischemia and reperfusion injury are significant causes of tissue damage in diseases and conditions such as heart attack, stroke and in organ transplantation. Recently, scientists at the National Institute of Environmental Health Sciences and Duke University, while investigating the phenomena of preconditioning, discovered and developed a highly effective method for protecting tissues from cell injury by ischemia by use of 12(S)=HpETE.

Previously developed treatments to prevent ischemic damage are greatly limited in their effectiveness. TPA, routinely used to dissolve blood clots, thereby allowing greater blood flow, does not prevent ischemic tissue injury. Aspirin has been shown to have only a small protective effect in the cardiovascular system. However, the above new method demonstrates a dramatic protective effect—up to 82% recovery in initial studies—when administered during injury, as seen in animal models. The protective effect of 12(S)-HpETE was discovered during investigation of the 12-lipoxygenase-related protective effect of ischemic preconditioning and, unlike other agents, 12(S)-HpETE has no known undesirable side effects.

Uses of such an invention may include treatment of tissue during angioplasty and treatment of organs intended for transplantation to limit the chance of damage.

This research was published in Circulation Research 76: 457–467, 1995.

Information about the patent application and pertinent information not yet publicly described can be obtained under a Confidential