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 CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Hanyu Ni, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number 301–435–0448 or e-mail your request, including your address to: *NiHanyu@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: August 21, 2006.

Meg Scofield,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E6–14185 Filed 8–25–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The REDS–II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors

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 the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The REDS–II Donor Iron Study: Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors.

Type of Information Collection Request: New.

Need and Use of Information Collection: Although the overall health significance of iron depletion in blood donors is uncertain, iron depletion leading to iron deficient erythropoiesis and lowered hemoglobin levels results in donor deferral and, occasionally, in mild iron deficiency anemia. Hemoglobin deferrals represent more than half of all donor deferral, deferring 16% of women. Several cross sectional studies of blood donors, using older measures of iron status in blood donors have indicated that female sex, frequent donation and not taking iron supplements are predictors of iron depletion. However, none of these studies have included racial/ethnic, anthropomorphic, or behavioral factors and none have evaluated the impact of newly discovered iron protein polymorphisms. The REDS–II Donor Iron Study is a longitudinal study of iron status in two cohorts of blood donors: A first-time/reactivated donor cohort in which baseline iron and hemoglobin status can be assessed without the influence of previous donations, and a frequent donor cohort, where the cumulative effect of additional frequent blood donations can be assessed. Each cohort's donors will donate blood and provide evaluation samples during the study period. We also propose to assess the baseline status of a group of first-time donors who are deferred for low hemoglobin on their first visit.

The primary goal of the study is to evaluate the effects of blood donation intensity on iron and hemoglobin status and assess how these are modified as a function of baseline iron/hemoglobin measures, demographic factors, and reproductive and behavioral factors. Hemoglobin levels, a panel of iron protein, red cell and reticulocyte indices will be measured at baseline and at a final follow-up visit 15–24 months after the baseline visit. A DNA sample will be obtained once at the baseline visit to assess three key iron protein polymorphisms. Donors will also complete a self-administered survey assessing past blood donation, smoking history, use of vitamin/mineral supplements, iron supplements, aspirin, frequency of heme rich food intake, and, for females, menstrual status and pregnancy history at these two time points. This study aims to identify the optimal laboratory measures that would predict the development of iron depletion, hemoglobin deferral, and/or iron deficient hemoglobin deferral in active whole blood and double red cell donors at subsequent blood donations. The data collected will help evaluate hemoglobin distributions in the blood donor population (eligible and deferred donors) and compare them with NHANES data. Other secondary objectives include elucidating key genetic influences on hemoglobin levels and iron status in a donor population as a function of donation history; and establishing a serum and DNA archive to evaluate the potential utility of future iron studies and genetic polymorphisms.

This study will develop better predictive models for iron depletion and hemoglobin deferral (with or without iron deficiency) in blood donors; allow for the development of improved donor screening strategies and open the possibility for customized donation frequency guidelines for individuals or classes of donors; provide important baseline information for the design of targeted iron supplementation strategies in blood donors, and improved counseling messages to blood donors regarding diet or supplements; and by elucidating the effect of genetic iron protein polymorphisms on the development of iron depletion, enhance the understanding of the role of these proteins in states of iron stress, using frequent blood donation as a model.

Frequency of Response: Twice.

Affected Public: Individuals.

Type of Respondents: Adult blood donors.

The annual reporting burden is as follows:

Estimated Number of Respondents:

Baseline Visit: 3,750.

Follow-up Visit: 1720.

Estimated Number of Responses per Respondent: 1.

Average Burden of Hours per Response:

Baseline Visit: 0.12.

Follow-up Visit: 0.1.

Estimated Total Annual Burden Hours Requested:

Baseline Visit: 450.

Follow-up Visit: 172.

The annualized cost to respondents is estimated at:

Baseline Visit: $8,100.

Follow-up Visit: $3,096 (based on $18 per hour).

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

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Blood donors at Baseline Visit	3,750	1	0.12	450
Blood donors at Follow-up Visit	1720	1	0.1	172
Total				622

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0075, or e-mail your request to *nemog@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 21, 2006.

Meg Scofield,

NHLBI Project Clearance Liaison Officer, National Institutes of Health.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Diagnostic and Therapeutic Strategies for Metastatic Hepatocellular Carcinoma by Targeting Osteopontin

Description of Technology: Cancer is one of the leading causes of death in United States and it is estimated that there will be more than half a million deaths caused by cancer in 2006. For the last decade breast and prostate cancer survival rate has significantly decreased thanks to contribution of screening, early detection and novel therapeutics. This success needs to be translated to other cancers as well, where there is a need of novel diagnostic and therapeutic strategies for successful disease management.

Osteopontin (OPN) is a well known serum prognostic marker for breast cancer. This technology identifies a 10kD residue of OPN as a potential prognostic marker and therapeutic target for metastatic hepatocellular carcinoma (HCC). Mechanistically, OPN has been shown to be a novel substrate for MMP–9 and the 10kD fragment is demonstrated to be a mediator of cell invasion and metastasis. Short synthetic peptides against OPN have been shown to block OPN mediated cell invasion, providing a novel therapeutic approach targeting OPN. Finally, polyclonal antibodies against the 10kD fragment of OPN have been developed that can be used for detection of OPN in physiological fluids of HCC patients. This technology provides a novel therapeutic and diagnostic strategy for the management of HCC patients using OPN.

Development Status: The technology is in the pre-clinical stage, animal studies are under way.

Inventors: Vivian A. Takafuji (NCI) *et al.*

Relevant Publications:

1. A manuscript relating to this invention has been submitted for publication and will be available once accepted.

2. J Kim, SS Ki, SD Lee, CJ Han, YC Kim, SH Park, SY Cho, YJ Hong, HY Park, M Lee, HH Jung, KH Lee, SH Jeong. Elevated plasma osteopontin levels in patients with hepatocellular carcinoma. Am J Gastroenterol. 2006 Jul 18; Epub ahead of print, doi: 10.1111/j.1572–0241.2006.00679.

3. QH Ye, LX Qin, M Forgues, P He, JW Kim, AC Peng, R Simon, Y Li, AI Robles, Y Chen, ZC Ma, ZQ Wu, SL Ye, YK Liu, ZY Tang, XW Wang. Predicting hepatitis B virus-positive metastatic hepatocellular carcinomas using gene expression profiling and supervised machine learning. Nat Med. 2003 Apr; 9(4):416–423.

Patent Status: U.S. Provisional Application No. 60/805,298 filed 20 Jun 2006 (HHS Reference No. E–201–2006/0–US–01).

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, Ph.D.; 301/451–7337; *boodenm@mail.nih.gov*.

Collaborative Research Opportunity: The NCI Laboratory of Human Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic and therapeutic strategies for metastatic hepatocellular carcinoma. Please contact Betty Tong at 301–594–4263 or *tongb@mail.nih.gov* for more information.