

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: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), 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 August 28, 2006, pages 50925–50926 and allowed 60-days for public comment. No comments were received in response to this notice. 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 current valid OMB control number.

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: 4,290, Follow up Visit: 2,040; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* Baseline Visit: 0.12, Follow up Visit: 0.1; and *Estimated Total Annual Burden Hours Requested:* Baseline visit: 515, Follow up Visit: 204. The annualized cost to respondents is estimated at: Baseline Visit: \$9,270, Follow up Visit: \$3,672 (based on \$18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE A.12.—ESTIMATES OF HOUR BURDEN AND ANNUALIZED COST TO RESPONDENTS

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Hourly wage rate (\$)	Estimated total annual burden hours requested
Blood donors at Baseline Visit	4,290	1	0.12	18	515
Blood donors at Follow-up Visit	2,040	1	0.1	18	204
Total	719

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.

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 to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 361, 6700 Rockledge Drive, Bethesda, MD 20892, or call non-toll free number 301-435-0075, or e-mail your request, including your address to nemog@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: January 25, 2007.

George Nemo,

Project Officer, NHLBI National Institutes of Health.

[FR Doc. E7-1587 Filed 1-31-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel; C.O.B.R.E SEP II.

Date: February 15, 2007.

Time: 6 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mamta Gautam-Basak, PhD, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Office of Review, 6701 Democracy Blvd., 1 Dem. Plaza, Room 1066, Bethesda, MD 20892, 301-435-0965, GautamM@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Special Emphasis Panel; Comparative Medicine Resources.

Date: February 21, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Steven Birken, PhD, Senior Research Scientist, Office of Review, National Center for Research Resources, One Democracy Plaza, Room 1078, 6701 Democracy Blvd., MSC-4874, Bethesda, MD 20892, 301-435-0815, birken@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel; SEPA 07' Review.

Date: March 7, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Gaithersburg Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Bonnie Dunn, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Dem. Blvd., Dem. 1, Room 1074, MSC 4874, Bethesda, MD 20892-4874, 301-435-0824, dunnbo@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS).

Dated: January 26, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-451 Filed 1-31-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 27, 2007.

Closed: 8:30 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Open: 9:30 a.m. to 5 p.m.

Agenda: The agenda will include Opening Remarks, Administrative Matters, Director's Report, NCMHD, NIAAA Health Disparities Update, Biennial Report on Compliance with NIH Inclusion Guidelines, Extramural Program Highlights, and other business of the Council.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Donna Brooks, Asst. Director for Administration, National Center on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, 301-435-2135, brooksd@ncmhd.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if