HHS will consider nominations of all qualified individuals to ensure that the Advisory Council includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the Advisory Council. Nominations shall state that the nominee is willing to serve as a member of the Council. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the Council to permit evaluation of possible sources of conflicts of interest.

In addition, nominees will be asked to provide detailed information concerning any employment, governance, or financial affiliation with any donor centers, recruitment organizations, transplant centers, and/or cord blood banks.

A nomination package should be sent in hard copy accompanied by an electronic version of the documents on compact disc. A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (i.e., what specific attributes recommend him/her for service in this capacity), and the nominee’s field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, return address, e-mail address, and daytime telephone number at which the nominator can be contacted.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.

Dated: February 27, 2009.

Elizabeth M. Duke,
Administrator.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; REDS–II Donor Iron Status Evaluation (RISE) 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 the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: REDS–II Donor Iron Status Evaluation (RISE) Study. Type of Information Collection Request: Revision of a currently approved collection. OMB control # 0925–0581. Expiration Date: 05/31/2009. 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. The RISE 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.

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 home 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 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.

This request for modification is to add eleven questions to the RISE study final visit questionnaire that will include questions about Restless Leg Syndrome (RLS) and pica, two disorders associated with iron deficiency. RLS is a neurologic movement disorder in which patients complain of crawling, aching or indescribable feelings in their legs or just have the need to move. Pica is an eating disorder defined as compulsive ingestion of non-food substances. Blood donation results in the removal of 200–250 mg of iron from the donor. It is well established that repeated blood donation can produce iron deficiency, yet the prevalence of RLS and pica among blood donors is unknown. The REDS–II RISE study subjects are an ideal study population for the investigation of RLS and pica in blood donors. About 2,400 subjects with variable donation intensity (e.g., frequency with which a person donates blood) are currently enrolled in the RISE.
Study. The iron status of all of these subjects is well characterized, including measurement of plasma ferritin and soluble transferrin receptor along with hemoglobin/hematocrit. These laboratory values allow each subject to be defined as (1) iron replete, (2) iron deficient without anemia or (3) iron deficiency anemia. The responses to these questions will be correlated with the laboratory test values to determine the relationship between blood donation and the development of RLS and pica and will establish its prevalence in these populations.

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: 2,340. Follow up Visit: 1,530; Estimated Number of Responses per Respondent: 1. Average Burden of Hours per Response: Baseline Visit: 0.37. Follow up Visit: 0.25; and Estimated Total Annual Burden Hours Requested: Baseline visit: 866. Follow up Visit: 383.

Comments Due Date: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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, Suite 10042, 6701 Rockledge Drive, Bethesda, MD 20892–7950, or call 301–594–2771, 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: February 27, 2009.

George Nemo,
NHLBI Project Officer, NHLBI, National Institutes of Health.
[FR Doc. E9–4836 Filed 3–6–09; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 Institute of General Medical Sciences Special Emphasis Panel. Minority Biomedical Research Score Applications.

Date: March 23–26, 2009.

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

Agenda: To review and evaluate grant applications.

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

Liaison: Contact Person: John J. LaFan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18, Bethesda, MD 20892, 301–594–2773, lafanjo@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel. Minority Biomedical Research Score Applications.

Date: March 26–27, 2009.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, pikbr@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 27, 2009.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.
[FR Doc. E9–4845 Filed 3–6–09; 8:45 am]