Dated: February 17, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill expected vacancies on the Advisory Council on Blood Stem Cell Transplantation.

The Advisory Council on Blood Stem Cell Transplantation was established pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended). In accordance with Public Law 92–463, the Council was chartered on December 19, 2006.

DATES: The agency must receive nominations on or before April 8, 2009.

ADDRESSES: All nominations should be submitted to the Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12–105, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, or UPS, mail delivery should be addressed to Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, Healthcare Systems Bureau, HRSA, at the above address.

FOR FURTHER INFORMATION CONTACT: Remy Aronoff, Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, at (301) 443–3264 or e-mail *Remy.Aronoff@hrsa.hhs.gov* or Robert Baitty, Director, Blood Stem Cell Transplantation Program, Division of Transplantation, at (301) 443–2612 or e-mail *Robert.Baitty@hrsa.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129). The Council is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council advises the Secretary and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program.

The Council shall, as requested by the Secretary, discuss and make recommendations regarding the C.W. Bill Young Cell Transplantation Program (Program). It shall provide a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation. The Council shall advise, assist, consult and make recommendations, at the request of the Secretary, on broad Program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory, requirements regarding informed consent for cord blood donation, accreditation requirements for cord blood banks, the scientific factors that define a cord blood unit as high quality, public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices, criteria for selecting the appropriate blood stem source for transplantation, Program priorities, research priorities, and the scope and design of the Stem Cell Therapeutic Outcomes Database. It also shall, at the request of the Secretary, review and advise on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy including compatibility of international regulations, and actions that may be taken by the State and Federal Governments and public and private insurers to increase donation and access to transplantation. The Advisory Council also shall make recommendations regarding research on emerging therapies using cells from bone marrow and cord blood.

The Council consists of up to 25 members, including the Chair. Members of the Advisory Council shall be chosen to ensure objectivity and balance, and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and to limit the number of members of the Advisory Council with any such affiliation.

The members and Chair shall be selected by the Secretary from outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists, hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

In addition, representatives from the Division of Transplantation of the Health Resources and Services Administration, the Department of Defense Marrow Recruitment and Research Program operated by the Department of the Navy, the Food and Drug Administration, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention serve as non-voting *ex officio* members.

Specifically, HRSA is requesting nominations for voting members of the Advisory Council on Blood Stem Cell Transplantation in these categories: Marrow donor centers and transplant centers representatives; cord blood banks and participating hospitals representatives; family members of bone marrow transplant and cord blood transplant recipients or family members of a patient who has requested assistance by the Program in searching for an unrelated donor; persons with expertise in bone marrow or cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; basic scientists with expertise in the biology of adult stem cells; researchers in hematology and transfusion medicine with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public. Nominees will be invited to serve a 2- to 6-year term beginning after January 1, 2010.

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.

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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 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.

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