DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Establishment of Advisory Council on Blood Stem Cell Transplantation and Solicitation of Nominations for Membership

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

ACTION: Notice of establishment of the Advisory Council on Blood Stem Cell Transplantation and Solicitation of Nominations for Membership.

SUMMARY: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended) and the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Administrator, HRSA, announces the establishment of the Advisory Council on Blood Stem Cell Transplantation by the Secretary, HHS. The Council will advise the Secretary on proposed C.W. Bill Young Cell Transplantation Program policies and other such matters as the Secretary determines.

Duration of this Council is for two years unless renewed by the Secretary, HHS. This notice also requests nominations for membership on the Council.

DATES: Nominations for members must be received on or before February 22, 2007.

ADDRESSES: All nominations should be submitted to the Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12C–06, 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:

I. Background and Authority

Establishment of the Council implements 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 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council shall advise 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.

II. Structure

The Council shall consist 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.

The Council also shall include as nonvoting members 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 and the National Institutes of Health. The Secretary may also appoint other non-voting ex officio members, or designees of such officials, as the Secretary deems necessary for the Council to effectively carry out its functions.

As necessary, subcommittees composed of members of the parent Council, may be established with the approval of the Secretary of HHS or his designee to perform specific functions within the Council's jurisdiction. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Members shall be invited to serve for a term of 2 years, and (assuming the Council's term is extended) each such member may serve as many as 3 consecutive 2-year terms, except that such limitations shall not apply to the

Chair of the Council (or the Chair-elect) or to the member of the Council who most recently served as the Chair; and one additional consecutive 2-year term may be served by any member of the Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank. A member of the Council may continue to serve after the expiration of the term of such member until a successor is appointed. In order to ensure the continuity of the Council, the Council shall be appointed so that each year the terms of approximately one-third of the members of the Council expires. Any member of the Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank will be prohibited from participating in any decision that materially affects the donor center, recruitment organization, transplant center, or cord blood bank. The number of members with such affiliations on the Council shall be limited. Meetings shall be held up to 3 times per year at the call of the Designated Federal Official or designee who shall approve the agenda and shall be present at all meetings.

A vacancy on the Council shall be filled in the manner in which the original appointment was made and shall be subjected to any conditions that applied with respect to the original appointment. An individual chosen to fill a vacancy shall be appointed for the remainder of the term of the member replaced. The vacancy shall not affect the power of the remaining members to execute the duties of the Council.

All members of HRSA advisory committees shall adhere to the conflict of interest rules applicable to Special Government Employees as such employees are defined in 18 U.S.C. section 202(a). These rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 12674 (as modified by Executive Order 12731).

Management and support services shall be provided by the Director, Division of Transplantation, Healthcare Systems Bureau, HRSA.

III. Compensation

Members shall be paid at a rate of $200 for each day they are engaged in the performance of their duties as members of the Council. Members shall receive per diem and travel expenses as authorized by 5 U.S.C. 5703, as amended, for persons employed intermittently in the Government service. Members who are officers or employees of the United States Government shall not receive compensation for service on the Council.

IV. Nominations

HHS will consider nominations of all qualified individuals to ensure that the Advisory Council includes the areas of subject matter expertise noted above (see ''Structure''). 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 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.

HHS 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. HHS also encourages geographic diversity in the composition of the Council.

All nomination information should be provided in a single, complete package within 30 days of the publication of this notice. All nominations for membership should be sent to the Executive Secretary of the Council at the address provided above.

Dated: January 16, 2007.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; 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 Fogarty International Center Advisory Board.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: February 5–6, 2007.

Closed: February 5, 2007, 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Open: February 6, 2007, 8:30 a.m. to 5 p.m.

Agenda: Discussions will focus on Fogarty International Center's early draft of the Strategic Plan.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Contact Person: Jean L. Flagg-Newton, PhD, Special Assistant to the Director, FIC, Fogarty International Center, National Institutes of Health, 9000 Rockville Pike, Building 31, Room B2C29, Bethesda, MD 20892, (301) 496–2968, *flaggnej@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on