



CHARTER

1. Council's Official Designation: The Council shall be known as the Advisory Council on Blood Stem Cell Transplantation ("Advisory Council").
2. Authority: The Advisory Council is required by Public Law 109-129, as amended by Public Law 117-15; Section 379 of the Public Health Service Act (42 U.S.C. 274k). The Advisory Council is governed by the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. 10), as amended.
3. Objectives and Scope of Activities: 42 U.S.C. 274k authorizes the operation of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI). The principal purpose of these programs is to increase the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood. The recommendations of the Advisory Council assist the Department of Health and Human Services (HHS) in overseeing these programs. The statute requires the Advisory Council's involvement in submitting reports to Congress.
4. Description of Duties: The Advisory Council shall advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary). The Advisory Council may transmit its recommendations through the Administrator of the Health Resources and Services Administration (HRSA) on matters related to the activities of the Program and NCBI.

The Advisory Council shall, as requested by the Secretary, discuss and make recommendations regarding the Program. In developing policies affecting the Program, the Secretary shall consult with the Advisory Council. 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 and donation. The Advisory Council may also review the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the Program.

5. Agency or Official to Whom the Committee Reports: The Advisory Council provides advice to the Secretary. The Advisory Council may also provide advice to the HRSA Administrator.
6. Support: Management and support services shall be provided by the Health Systems Bureau of HRSA.

7. Estimated Annual Operating Costs and Staff Years: Estimated annual cost for operating the Advisory Council, including compensation and travel expenses for members, but excluding staff support, is \$70,000. The estimate of annual person-years of staff support required is .55 FTE at an estimated annual cost of \$199,000.
8. Designated Federal Officer: A full-time federal employee, appointed in accordance with agency procedures, will serve as the Designated Federal Officer (DFO) (or designee) and ensure that all procedures are within applicable statutory, regulatory, and Department of Health and Human Services (HHS) General Administration Manual directives. The DFO (or designee) determines adjournment to be in the public interest, and chairs meetings when directed to do so by the HRSA Administrator.
9. Estimated Number and Frequency of Meetings: The Advisory Council shall convene at least two times each calendar year. Notice of all meetings shall be given to the public. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act of 1972 (5 U.S.C. 10). Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.
10. Duration: Continuing.
11. Termination: Unless rechartered by appropriate action prior to its expiration, the Advisory Council's charter will terminate 2 years from the date the charter is filed.
12. Membership and Designation: The Advisory Council shall consist of up to 15 members, who are Special Government Employees, and four ex-officio, non-voting members. Members and the Chair shall be appointed by the Secretary 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 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.

Concurrent service on Advisory Council and the Board of Directors, or other governing bodies, of organizations who hold a contract for the Program, is not permitted. To the extent practicable, committee Special Government Employees should represent the diversity (e.g., racial, minority, ethnic, gender, geographic) of those served by the Program.

The members and Chair shall be appointed 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 public.

The Advisory Council also includes as non-voting, ex-officio members, representatives from the Division of Transplantation of HRSA, 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.

Special Government Employees shall be invited to serve for a term of 2 years, and each such member may serve as many as three consecutive 2-year terms, except that such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and one additional consecutive 2-year term may be served by any member of the Advisory 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 Advisory 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 Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire. Any member of the Advisory Council who has 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 Advisory Council shall be limited.

13. Subcommittees: Standing and ad hoc subcommittees, composed of members of the parent Advisory Council, may be established with the approval of the DFO to perform specific functions within the Advisory Council's jurisdiction. Subcommittees must report back to the parent Committee and do not provide advice or work products directly to HHS or HRSA. The Department's Committee Management Officer will be notified upon the establishment of each subcommittee's name, membership, function, and estimated frequency of meetings.
14. Recordkeeping: Records of the Advisory Council, formally and informally established subcommittees, or other subgroups of Advisory Council, shall be handled in accordance with General Records Schedule 6.2, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. § 552.
15. Filing Date: February 19, 2023

Approved:

February 15, 2023

Date

/Carole Johnson/

Carole Johnson
Administrator