NATIONAL MARROW DONOR PROGRAM®
MEMBER CORD BLOOD BANK PARTICIPATION CRITERIA

The National Marrow Donor Program® (NMDP) has established Cord Blood Bank Participation Criteria to address qualification of cord blood banks for participation in the NMDP Network. NMDP member cord blood banks (CBB or bank) must follow these Participation Criteria, in addition to cord blood bank accreditation requirements from NetCord-FACT or AABB, requirements to participate in the NMDP Investigational New Drug (IND) application for distribution of unlicensed cord blood units (HPC(CB)) in the United States, and NMDP Standards, policies, procedures, and Participation Agreements that may impose additional requirements for cord blood banks and support laboratories. HPC(CB) distributed under a Biologics License Application (BLA) will be considered to have met all relevant NMDP IND requirements.

ADMINISTRATION

1. Bank must be qualified to participate under the NMDP Food and Drug Administration (FDA)-accepted IND that utilizes the 10-CBA protocol. *(BB-IND #7755-0088: A Centralized Cord Blood Registry to Facilitate Allogenic, Unrelated Donor Umbilical Cord Blood Transplantation).*

2. Bank must maintain accreditation by either AABB or NetCord-FACT for cord blood banking.

3. Bank should comply with the regulations outlined in the FDA guidance, Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic System (as applicable and as may be amended or replaced from time to time) that provides the recommendations for submission of a BLA under Title 21 of the Code of Federal Regulations.

4. Bank must comply with NMDP participation requirements, which include NMDP Standards, policies, procedures, and terms of the Participation Agreement.

5. Bank must comply with applicable World Marrow Donor Association (WMDA) Standards.

6. Bank must meet established Continuous Process Improvement (CPI) criteria.

7. Bank must participate in the NMDP member annual re-qualification process and provide documentation that validates compliance with NMDP Participation Requirements and member qualification requirements.

8. Bank must submit NMDP and CIBMTR data as required.

9. Bank must participate in proficiency testing, as defined by the NMDP or by its accrediting body (NetCord-FACT or AABB).

10. Bank must promptly report to the NMDP any significant changes in personnel (including, but not limited to, the medical director, coordinator, laboratory director, and quality manager), facilities, subcontractors, accreditations, FDA licensure, FDA registration, or support services. Any change to AABB or NetCord-FACT accreditation status, IND status, FDA licensure, or FDA registration must be reported to the NMDP no later than 15 days after receipt of notice.

FACILITY CHARACTERISTICS

11. Bank must have experience in cord blood recruitment and management of cord blood maternal donors.

12. Bank must have adequate staff, resources, space, equipment, and supplies to perform and manage its recruitment activities, HPC(CB) manufacturing activities, and sample management.

13. Bank must have secure record storage.

14. Bank must use a secure information management system, exchange data, and respond to search requests according to NMDP requirements using NMDP-provided software.

15. Bank should have a designated, independent quality unit to audit, monitor, and authorize release of HPC(CB) as defined in facility-specific procedures.

16. Bank must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.

PERSONNEL

17. Bank must designate a medical director who is a licensed physician, qualified by training and experience to perform or supervise HPC(CB) activities and:

    a. Has post-doctoral training in hematopoietic cell transplantation, cord blood, blood or tissue banking, basic or clinical immunology/immunohematology or cryobiology.

    b. Participates annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour per year).

    c. Assures that physician designees are trained and qualified; any responsibility(ies) of the center medical director may be fulfilled by a designated center physician.

18. Cord blood bank medical director (or physician designee) is responsible for:

    a. Review of the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transplantation.

    b. Recruitment, informed consent, evaluation, and follow-up of the maternal donor.

    c. Participation in the development of the procedures for the collection, processing, testing, banking, and release of HPC(CB).

    d. Evaluation of the medical history and testing results, and documentation of the review prior to listing the HPC(CB) unit with the NMDP.

19. Bank must provide daily and emergency coverage by designated coordinator(s), sufficient in number to meet the needs of the CBB's activities.

20. Bank must comply with NMDP training requirements.

SUPPORT SERVICES

21. Bank must provide to the NMDP a list of all cord blood collection facilities operating under written agreements with the CBB to collect cord blood. These collection facilities must:

    a. Be accredited by Centers for Medicare and Medicaid Services (CMS) or other organizations with deemed status, and/or be birth centers accredited by the Commission for the Accreditation of Birth Centers (CABC).

    b. Use a designated area adequately equipped to collect and temporarily store HPC(CB).

    c. Have written procedures for the collection of HPC(CB).

22. Bank must ensure collections that occur at non-fixed sites are collected by personnel appropriately trained to meet the CBB's requirements.

23. Bank must use laboratory facilities that are licensed, certified, or accredited in accordance with applicable U.S. federal and state laws and regulations and NMDP requirements which include:

    a. HLA typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Foundation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for initial typing. Initial typing on HPC(CB) added after a bank has been approved for membership must use / must be done using DNA methodology at a minimum of low resolution for HLA-A -B, -C and high resolution for HLA-DRB1. Confirmatory typing should be performed at a laboratory designated by the NMDP.

    b. Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) for all clinical laboratory tests required by the NMDP, as applicable.

    c. Laboratory(ies) used for Infectious Disease Marker (IDM) testing to assist in determining donor eligibility must:

        1. Be certified by CMS.

        2. Be registered by the FDA as an establishment that manufactures human cells, tissues, and cellular and tissue-based products (HCT/Ps) for umbilical cord blood.

        3. Use appropriate FDA licensed, approved, or cleared donor screening test kits for use in testing HCT/P donors and follow manufacturer's requirements for testing.

24. Bank must notify the NMDP of subcontractor arrangements used by the CBB, including those used for processing, cryopreservation, storage, or distribution.

25. Bank must have prompt technical and operational support for information systems management.

POLICIES AND PROCEDURES

26. HPC(CB) collected after the bank receives NMDP approval for NMDP membership must adhere to A00597, *NMDP Current Inventory Requirements for New Cord Blood Units.*

27. Bank must obtain signed, informed consent for HPC(CB) collection while the maternal donor is able to concentrate on the information, before the maternal donor goes into active labor. Consent for donation, testing, and storage must be obtained no later than seven days after collection of the unit.

28. Bank must have procedures to inform, counsel, and document counseling of the maternal donor regarding any clinically significant abnormal findings.

29. Bank must meet Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP), including but not limited to a quality system that includes:

    a. A quality plan.

    b. An internal auditing system.

    c. Procedures and processes to address all steps in the manufacture of HPC(CB), including collection, donor screening and testing, processing, storage, labeling, packaging, and distribution.

30. Records shall be maintained to ensure the identification and traceability/trackability of each HPC(CB) unit and all related samples from their initial source, through each processing and testing step to its final disposition, and from final disposition, through each processing and testing step, to the initial source. Bank must retain records per AABB and/or NetCord-FACT requirements. In addition, bank must retain the following records indefinitely:

    a. Maternal consent documents (collection, screening, testing, and storage of cord blood).

    b. Maternal health history and family medical history screening and eligibility determinations, including reasons for permanent or temporary deferral.

    c. Infectious disease testing and other laboratory results.

    d. Documentation of abnormal findings and notification/counseling of relevant parties.

    e. Records pertaining to collection, processing, labeling, packaging, storage, distribution and final disposition of collected product.

    f. Records pertaining to the traceability and tracking of all aspects of the manufacture of the HPC(CB) product performed at the site with the exception of facility cleaning and sanitation records which are retained minimally for 3 years.

    g. Records of adverse reactions.

31. Bank must have processes and procedures in place to promptly identify, investigate, report, correct and prevent, if applicable, the following per NMDP requirements:

    a. Adverse events

    b. Deviations

    c. Complaints

    d. Nonconforming products, materials, or services

    e. Corrective actions and preventive actions

32. Bank must maintain a system of strict confidentiality of records to protect the privacy of the maternal donor, the infant donor, patients, and all related records.

APPLICANT MEMBER BANKS

At the time of initial application, applicant bank must meet the following additional criteria:

33. Bank must have a minimum of 500 cryopreserved HPC(CB) units available for listing on the Be the Match Registry®.

34. Bank must be currently collecting, processing and storing HPC(CB) designated for unrelated transplantation.

35. Bank must have been approved and participating with the NMDP as an IND-approved (non-member) bank for at least six months.

36. Bank must undergo an on-site audit of its operations by NMDP staff.

NMDP may, in its discretion, approve deviations from these Criteria on a case-by-case basis upon demonstration by the bank of extenuating circumstances.