

NATIONAL MARROW DONOR PROGRAM®

CORD BLOOD BANK PARTICIPATION CRITERIA

Cord Blood Bank Criteria have been adopted by the NMDP to ensure that stem cells derived from cord blood are obtained, tested and stored according to accepted procedures, and to ensure they are viable and free from infectious diseases. All Cord Blood Banks (CBB) participating in the NMDP must continuously meet these criteria and demonstrate compliance with NMDP Standards. These criteria are subject to change without notification due to NMDP Standards or Policy, U.S. Food and Drug Administration regulation, or regulation by any other agencies.

FACILITY CHARACTERISTICS

1. The CBB shall have demonstrated experience in the recruitment and management of cord blood collections, including education, counseling, confidentiality issues, and medical screening.
2. The CBB shall have adequate and secure facilities for processing, storing, and retrieving cord blood units and samples.
3. The CBB shall have a designated site for management activities and locked file cabinets for record storage.
4. The CBB shall have an information management system and merge data according to NMDP requirements using the NMDP-provided software, CORD Link®, or center-specific software that meets NMDP specifications. Center must also provide on-site technical support for computer related issues.
5. The CBB shall have and maintain accreditation by either AABB or Foundation for the Accreditation of Cellular Therapy (FACT)/NetCord for cord blood banking. Any change to accreditation status must be reported to the NMDP promptly, but no later than 15 days after the bank receives notice of its accreditation status change(s).

POLICIES AND PROCEDURES

6. The CBB must have a minimum of 100 cryopreserved cord blood units that:
 - are typed for HLA-A, B (serology or DNA-based) and DRB1 (DNA-based).
 - are typed for ABO group and Rh type.
 - are cultured for microbial contamination. Antibiotic sensitivities must be performed on each positive culture with these results available prior to the use of the cells.
 - are labeled appropriately to permit traceability and trackability, including the date of collection.
 - are collected and stored in accordance with the Standards of the AABB or the Foundation for the Accreditation of Cellular Therapy (Netcord/FACT).

- have at least one and preferably two cryopreserved aliquots available for additional testing of DNA, viability, microbial contamination, or another assay as required by the NMDP.
 - have results available on the maternal infectious disease testing.
 - have record of a maternal medical history prior to or within 15 days following the collection of the unit. The history must be evaluated for acceptability prior to release of the cord blood unit for infusion.
 - have the volume and nucleated cell count documented.
7. The CBB must have written procedures for (maternal) donor recruitment, selection, obtaining maternal health and family history, infectious disease marker testing; and cord blood processing, labeling, storage, and transportation.
 8. The CBB must obtain informed consent of the mother for the collection of the unit and donation of the unit to a cord blood bank prior to, or within seven days after, the collection of the unit.
 9. The CBB must have donor selection, donor suitability, CBU collection, processing, storage, issuance, and distribution procedures which meet or exceed the requirements set forth in the NMDP IND.
 10. The CBB shall have written policies and procedures for the release and issue of cord blood units and for the return to inventory of unused cryopreserved units.
 11. The CBB shall have written procedures for the qualification of cord blood collection facilities and personnel.

CORD BLOOD BANK PERSONNEL

12. The CBB must have a Medical Director:
 - Who is a licensed physician
 - Who is responsible for compliance with NMDP Standards and for the preparation of protocols for recruitment, evaluation and follow-up of the potential donor; protocols for informed consent; and protocols for the collection, testing, banking selection, and release of the unit.
 - Shall be responsible for reviewing the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transfusion or transplantation.
 - Shall have post-doctoral training in hematopoietic cell transplantation, blood or tissue banking, basic or clinical immunology, immunohematology or cryobiology.
 - Shall participate regularly in educational activities related to the field of hematopoietic progenitor cell collection, processing, transplantation or cord blood banking (at least one CME credit hour or non-U.S. equivalent per year).

13. The CBB shall designate a coordinator to work with the NMDP.
14. The CBB shall also have staff sufficient to manage daily activities, providing for staff coverage each working day, and emergency availability.
15. The CBB shall identify an advocate for the biologic mother of the cord blood donor and offer the advocate's services.
16. The CBB shall have adequately trained and competent personnel available to perform processing, cryopreservation, storage, and retrieval of cord blood units and samples.

SUPPORT SERVICES

17. The CBB shall have collaborative agreements with facilities collecting cord blood units, and must provide to the NMDP a list of all cord blood collection facilities operating in association with the CBB. These collection facilities must:
 - be accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-U.S. equivalent.
 - have an adequate number of trained personnel.
 - have a designated area adequately equipped to collect cord blood units.
 - have written procedures for the collection of the unit.
18. The CBB must designate a laboratory certified by CAP (College of American Pathologists) for microbial contamination assays.
19. The CBB must designate a laboratory certified by CLIA (or non-US equivalent) for infectious disease marker testing, ABO/Rh typing, red cell antibody screening if performed, and for other tests required by the NMDP.
20. The CBB must designate an HLA typing laboratory (ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Foundation for Immunogenetics (EFI) for techniques required by NMDP.
21. The CBB shall have technical support for computer-related issues.
22. If applicable, the CBB must notify the NMDP of other subcontractor arrangements utilized by the CBB, including processing, cryopreservation, storage or distribution.