

NATIONAL MARROW DONOR PROGRAM®
CORD BLOOD BANK PARTICIPATION CRITERIA

National Marrow Donor Program® (NMDP) has established Cord Blood Bank (CBB) Participation Criteria to address qualification of banks for participation in the NMDP Network. NMDP has also established Standards, policies, procedures, and Participation Agreements that may impose additional requirements for banks.

FACILITY CHARACTERISTICS

1. Bank must be an establishment registered with the U.S. Food and Drug Administration (FDA) as a manufacturer of human cells, tissues, and cellular and tissue-based products (HCT/Ps).
2. Bank must have demonstrated experience in the recruitment of cord blood donors and management of cord blood collections, including education, counseling, ensuring confidentiality, and medical screening.
3. Bank must have a minimum of 100 cryopreserved cord blood units (CBUs).
4. Bank must have adequate and appropriate resources to support its activities.
5. Bank must use adequate and secure facilities for processing, storing, and retrieving cord blood units and samples.
6. Bank must use a secure environment for confidential record storage.
7. Bank must use a secure information management system and exchange data according to NMDP requirements using the NMDP-provided software, CORD Link®, or bank-specific software that meets NMDP specifications.

PERSONNEL

8. Bank must have a Medical Director who:
 - a. Is a licensed physician;
 - b. 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, processing, testing, banking, selection, and release of the unit;
 - c. Is responsible for reviewing the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transplantation;
 - d. Has post-doctoral training in hematopoietic cell transplantation, blood or tissue banking, basic or clinical immunology, immunohematology or cryobiology;
 - e. Participates annually 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).
9. Bank must use trained and competent personnel to perform processing, cryopreservation, storage, and retrieval of cord blood units and samples.
10. Bank must provide daily and emergency coverage by designated coordinator(s), who are proficient in English, and sufficient in number to meet the needs of the bank's activities.

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11. Bank must comply with NMDP training requirements.
12. Bank must document staff and volunteer training, continuing education, and continued competency for relevant skills.

SUPPORT SERVICES

13. Bank must have and follow written collaborative agreements with facilities that routinely collect 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:
 - a. Be accredited by The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) or non-U.S. equivalent;
 - b. Have an adequate number of trained personnel;
 - c. Use a designated area adequately equipped to collect and temporarily store cord blood units;
 - d. Have written procedures for the collection of cord blood units;
 - e. Not compensate or charge donors for any aspect of the collection or donation of the cord blood unit; and
 - f. Not coerce maternal donors to donate cord blood.
14. Bank must use facilities that are licensed, certified, or accredited in accordance with U.S. federal and state laws and regulations (or non-U.S. equivalent for non-U.S. banks). Additional requirements include:
 - a. Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS), (or non-U.S. equivalent) for tests required by the NMDP
 - b. IDM laboratory to determine eligibility must be registered by the FDA as an establishment that manufactures human cells, tissues, and cellular and tissue-based products (HCT/Ps) and use FDA licensed, approved, or cleared donor screening test kits for use in testing HCT/P donors and follow manufacturer's requirements for testing
 - c. Laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Foundation for Immunogenetics (EFI) for HLA typing required by the NMDP
15. Bank must notify the NMDP of subcontractor arrangements used by the CBB, including processing, cryopreservation, storage or distribution.
16. Bank must have prompt technical support available for information technology systems.

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POLICIES AND PROCEDURES

17. All cord blood units intended for use in unrelated donor transplantation must:
 - a. Be typed for HLA-A, B (serology or DNA-based) and DRB1 (DNA-based);
 - b. Be typed for ABO group and Rh type;
 - c. Be negative for microbial contamination;
 - d. Be labeled appropriately to permit traceability, including the date of collection;
 - e. Be collected and stored in accordance with the Standards of AABB or the Foundation for the Accreditation of Cellular Therapy (Netcord/FACT);
 - f. Have at least two segments each containing at least 100 uL at the time of cryopreservation available for additional testing of DNA, viability, microbial contamination, or another assay as required by the NMDP;
 - g. Have results available on the maternal infectious disease testing;
 - h. Have record of a maternal medical history prior to or within 30 days following the collection of the unit;
 - i. Must have all records reviewed by the Medical Director or designee prior to listing the CBU with the NMDP and re-evaluated prior to the release of the CBU for infusion;
 - j. Have the volume and nucleated cell count documented;
 - k. Have been collected for the purpose of unrelated transplantation; and
 - l. Not be stored with non-human sources or blood components.
18. Bank must obtain informed consent from the biologic mother for collection, testing, and donation of the cord blood unit to a cord blood bank for use in unrelated donor cellular therapies.
19. Bank must obtain consent for CBU collection before delivery. Consent for donation and banking must be obtained no later than seven days after collection of the unit.
20. Bank must have procedures to inform, counsel, and document counseling of maternal donor regarding any abnormal findings.
21. Bank must meet Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP), including but not limited to:
 - a. Standard Operating Procedures (SOPs) for qualification of collection facilities and personnel, maternal donor recruitment, selection, collection, processing, infectious disease marker testing, disposition, suitability, labeling, storage, release, transportation and return to inventory of unused cyropreserved units;
 - b. Internal auditing and corrective action systems; and
 - c. A quality plan.
22. Bank must establish a system of strict confidentiality that meets or exceeds NMDP requirements for the protection of privacy of donors (including the maternal donor), patients and recipients.

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ADMINISTRATION

23. Bank must comply with NMDP Participation Requirements, which include NMDP Standards, Policies, Procedures, and terms of the Participation Agreement.
24. Bank must comply with applicable World Marrow Donor Association (WMDA) Standards.
25. Bank must meet established Continuous Process Improvement (CPI) criteria.
26. Bank must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis.
27. Bank must complete and submit NMDP data forms as required.
28. Bank must participate in proficiency testing, as defined by NMDP.
29. Bank must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.
30. Bank must promptly report to the NMDP any significant changes in personnel (including, but not limited to, the medical director, coordinator, laboratory director, quality manager), facilities, accreditations, or support services.
31. Bank must 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, not later than 15 days after the bank receives notice of its accreditation status change(s).

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