

NATIONAL MARROW DONOR PROGRAM® APHERESIS CENTER PARTICIPATION CRITERIA

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

FACILITY CHARACTERISTICS

1. Center 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. Center must have experience in the collection of cellular components by apheresis, and must have performed at least three collections of mononuclear cells by apheresis in the past year.
3. Center must have adequate and appropriate resources, equipment, supplies, and pharmaceuticals to support its collection and associated management activities.
4. Center must have a designated site for the management of collection activities and a secure environment for confidential record storage.
5. Center must have at least two consecutive days available per week to manage NMDP collection activity.

PERSONNEL AND APHERESIS COLLECTION TEAM

6. Center must have a Medical Director who:
 - a. Is a licensed physician;
 - b. Has post-doctoral training in hematopoietic cell collection or transplantation;
 - c. Has performed or supervised at least ten cellular product apheresis collection procedures within the last three years; and
 - d. Participates annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour or non-U.S. equivalent per year).
7. A licensed physician must be available for direct or telephone discussion throughout mobilizing agent administration and donor monitoring. The physician must be qualified by knowledge and training in the administration of the mobilizing agent and monitoring its effect on donors or patients.
8. A licensed physician or appropriately-licensed mid-level practitioner must perform and/or evaluate a complete medical history, physical examination, and laboratory evaluation of the donor to determine if the donor is an acceptable candidate for donation by apheresis. For purposes of this criterion, an appropriately licensed mid-level practitioner is defined as a physician assistant, nurse practitioner, or advanced practitioner who provides primary patient care with physician oversight. The evaluation and test results must be reviewed and approved by the Donor Center Medical Director and Apheresis Center Medical Director.
9. The apheresis center physician is responsible for protecting the safety of the donor and product(s), and for identifying conditions in the donor that may be transmissible by transfusion or transplantation.

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10. Apheresis center physician supervising the apheresis collection must:
 - a. Be qualified by training and experience;
 - b. Have at least one year experience in the collection procedure;
 - c. Be available on-site or by telephone for the duration of the collection procedure(s) and for follow-up as needed; and
 - d. Participate annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour or non-U.S. equivalent per year).
11. A licensed physician qualified by training and experience must place any required central venous catheters.
12. Center must use apheresis collection staff:
 - a. Trained in the administration of mobilizing agents to donors; and
 - b. Experienced in the collection and handling of mononuclear cells by apheresis and management of apheresis donors including those with central venous catheters.
13. Center must provide daily and emergency coverage by a designated coordinator(s) who is proficient in English, and sufficient in number to meet the needs of the center's activities.
14. Center personnel must comply with NMDP training requirements, including but not limited to confidentiality training.
15. Center must document staff and volunteer training, continuing education, and continued competency for relevant skills.

SUPPORT SERVICES

16. Center must use a hospital that is accredited by The Joint Commission (TJC) the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), or non-U.S. equivalent, for placement of any required central venous catheters and subsequent collection.
17. Center 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. centers). 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. Laboratory used for measuring the quantity of CD34+ cells in the product collected must participate in a proficiency testing program
 - c. IDM laboratory to determine donor eligibility must be 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) 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.

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POLICIES AND PROCEDURES

18. Center must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP), including but not limited to:
 - a. Standard Operating Procedures (SOPs) for donor evaluation (including peripheral venous access), mobilizing agent administration, product collection (including prevention and minimization of citrate toxicity), management and reporting of adverse events, testing, storage, labeling, intracenter transport of product, emergency care for the donor, and maintenance of apheresis equipment;
 - b. Internal auditing and corrective action systems; and
 - c. A quality plan.
19. Center shall have a written policy on the assessment and placement of central venous catheters.
 - a. The written policy must state that central venous catheters shall only be used when peripheral venous access:
 - is not deemed feasible after skilled assessment
 - cannot be obtained; or
 - has failed.
 - b. The policy shall also state that justification for placement of a central venous catheter must be documented for each NMDP donor.
20. Center must establish a system of strict confidentiality that meets or exceeds NMDP requirements for the protection of privacy of potential donors, donors, patients, and recipients.
21. Center must provide the donor with post-donation care instructions that include appropriate contact names and phone numbers.

ADMINISTRATION

22. Center must comply with NMDP Participation Requirements, which include NMDP Standards, Policies, Procedures, and terms of the Participation Agreement.
23. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.
24. The Center must meet established Continuous Process Improvement (CPI) criteria.
25. Center must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis.
26. Center must complete and submit NMDP data forms as required.
27. Center must have and follow written Procedures of Interaction (POI) developed in collaboration with NMDP Donor Center(s).

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28. Center must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.
29. Center must promptly report to the NMDP any significant changes in personnel, facilities, accreditations, or support services.
30. Center must promptly report to the NMDP a change of accreditation status for Hematopoietic Progenitor Cell Collection from the Foundation for Accreditation of Cellular Therapy (FACT), AABB or non-U.S. equivalent, not later than 15 days after receipt of notice.

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