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, guidelines, protocols, 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 is a licensed physician qualified by training and experience to supervise mononuclear cell collections:
   a. Has post-doctoral training in hematopoietic cell collection or transplantation;
   b. Has performed or supervised at least ten cellular product apheresis collection procedures within the last three years; and
   c. 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. Administration of mobilization agents shall be under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents.
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 prospective donor to determine if they are 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 medical director 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.

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 accredited by an organization granted deemed status by Centers for Medicare and Medicaid Services (CMS), (or non-U.S. equivalent for non-U.S. centers), 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) and NMDP requirements which 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 have documented proficiency for CD34+ testing.

c. IDM laboratory used to determine donor eligibility must be registered with the 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.

POLICIES AND PROCEDURES

18. Center must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP), including but not limited to:

    a. Center must maintain written Standard Operating Procedures (SOPs) to address at least the following:

        i. donor evaluation (including peripheral venous access)
        ii. mobilizing agent administration
        iii. product collection (including prevention and minimization of citrate toxicity)
        iv. management and reporting of adverse events
        v. testing
        vi. storage
        vii. labeling
        viii. intra-center transport of product
        ix. emergency care for the donor
        x. maintenance of apheresis equipment
        xi. internal auditing
        xii. Corrective actions and preventive actions

    b. Center must have a quality assurance program designed at minimum to promptly identify, process, report, and prevent, if applicable, the following per NMDP requirements:

        i. Adverse reactions
        ii. Deviations
        iii. Complaints
        iv. Nonconforming products, materials, or services
        v. Corrective actions and preventive actions

    c. Center must maintain relevant records to ensure the identification and traceability/trackability of each donor and all related cellular therapy products and samples from their initial source through each processing and testing step.

    d. Center must retain records in accordance with NMDP Standards.

19. Center must have a written policy on the assessment and placement of central venous catheters.

    a. The written policy must state that central venous catheters must only be used when peripheral venous access:

        i. is not deemed feasible after skilled assessment
        ii. cannot be obtained, or
        iii. has failed.

b. The policy must also state that placement of central venous catheters must require a written justification

c. Adequacy of line placement must be verified prior to use.

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, guidelines, protocols, 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).
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.