NATIONAL MARROW DONOR PROGRAM®
COLLECTION CENTER PARTICIPATION CRITERIA

National Marrow Donor Program® (NMDP) has established Collection 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 accredited by (an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS), or non-U.S. equivalent).
2. Center must have adequate and appropriate resources, equipment, supplies, and pharmaceuticals to support its collection and associated management activities.
3. Center must have a designated site for management of collection activities and a secure environment for confidential record storage.
4. Center must have a surgical operating room and a medical intensive care unit.

PERSONNEL AND MARROW COLLECTION TEAM

5. Center must have a medical director who:
   a. Is a licensed physician qualified by training and experience to supervise HPC, Marrow [HPC(M)] collections;
   b. Has post-doctoral training in hematopoietic cell collection or transplantation;
   c. Has at least one year experience in the [HPC(M)] collection procedure; 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).
6. The center medical director is responsible for reviewing the medical evaluation of the prospective donor for risks of donation and evidence of disease transmissible by transplantation.
7. A licensed physician or appropriately-licensed mid-level practitioner must perform and/or evaluate a complete medical history and physical and laboratory examinations of the prospective donor to determine if they are an acceptable candidate for HPC(M) donation. 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 Collection Center Medical Director.
8. The physician responsible for performing the HPC(M) collection must:
   a. Have performed at least 10 prior collections of HPC(M) for transplantation with at least three collections in the previous three years;
   b. Maintain documented operating room privileges at the collection center.
   c. Must be present for the duration of the marrow collection.

9. Any person assisting in the HPC(M) aspiration (physician, physician assistant, nurse, technician) must have documented, adequate training in HPC(M) collections for transplantation.
10. Center must use an experienced team that has collected HPC(M) at least three times in the past three years at the center.
11. Center must administer anesthesia under supervision of a licensed, board certified anesthesiologist.
12. Physician is responsible for determining the donor's health is appropriate for discharge. Donor shall be admitted and discharged from the collection center the same day, unless the medical status precludes it.
13. Center 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 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 shall have the capability to perform the NMDP HPC(M) collection in a timely fashion.
17. Center must have irradiated and leukoreduced blood components available in the event that the use of allogeneic blood cannot be avoided. Allogeneic blood should be transfused to the donor only in situations of unexpected blood loss.
18. 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 clinical laboratory tests required by the NMDP
    b. 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

19. Center must provide the donor with post-donation care instructions that include appropriate contact names and phone numbers.
20. Center must verify that the donor has autologous red cell units, available prior to the HPC(M) collection, appropriate to the anticipated volume of HPC(M) to be collected.
21. Center must establish a system of strict confidentiality that meets or exceeds NMDP requirements for the protection the privacy of potential donors (registry members), donors, patients, and recipients.
22. Center must maintain written Standard Operating Procedures (SOPs) to address at least the following:
    a. donor evaluation
    b. product collection
    c. management of adverse events
    d. testing
    e. storage
    f. labeling
    g. intra-center transport of product
    h. emergency care for the donor
    i. internal auditing
    j. corrective and preventive actions
23. Center must maintain 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.
24. Center must retain records in accordance with NMDP Standards.
25. Center must have a quality assurance program designed at minimum to promptly identify, process, report, and prevent, if applicable, the following per NMDP requirements:
    a. Adverse reactions
    b. Deviations
    c. Complaints
    d. Nonconforming products, materials, or services
    e. Corrective actions and preventive actions

ADMINISTRATION

26. Center must comply with NMDP participation requirements, which include NMDP Standards, policies, procedures, guidelines, protocols, and terms of the Participation Agreement.
27. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.
28. Center must meet established Continuous Process Improvement (CPI) criteria.
29. Center must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis.
30. Center must complete and submit NMDP data forms as required.
31. Center must have and follow written Procedures of Interaction (POI) developed in collaboration with NMDP Donor Center(s).
32. Center must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.
33. Center must promptly report to the NMDP any significant changes in personnel, facilities, accreditations, or support services.

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