

# **NATIONAL MARROW DONOR PROGRAM®**

## **COLLECTION CENTER PARTICIPATION CRITERIA**

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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, and Participation Agreements that may impose additional requirements for centers.

### **FACILITY CHARACTERISTICS**

1. Center must be accredited by The Joint Commission (TJC), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), or non-US 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;
  - b. Has post-doctoral training in hematopoietic cell collection or transplantation;
  - c. Has at least one year experience in the marrow 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 collection center physician is responsible for reviewing the medical evaluation of the 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 donor to determine if the donor is an acceptable candidate for marrow 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 lead physician performing the marrow collection must:
  - a. Have performed at least 12 prior collections of marrow for transplantation with at least four collections in the previous three years;
  - b. Maintain documented operating room privileges at the collection center; and
  - c. Must be present for the duration of the marrow collection.

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9. Any person assisting in the marrow aspiration (physician, physician assistant, nurse, technician) must have documented, adequate training in marrow collections for transplantation.
10. Center must use an experienced team that has collected marrow at least four times in the past year 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.
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 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.
17. Center must use facilities 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) for clinical laboratory tests required by the NMDP
  - b. IDM laboratory to determine donor eligibility must 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 provide the donor with post-donation care instructions that include appropriate contact names and phone numbers.
19. Center must verify that the donor has autologous red cell units, available prior to the marrow collection, appropriate to the anticipated volume of marrow to be collected.
20. Center must establish a system of strict confidentiality that meets or exceeds NMDP requirements for the protection the privacy of potential donors, donors, patients, and recipients.
21. Center must maintain written Standard Operating Procedures (SOPs) to address at least the following: donor evaluation, product collection, management and reporting of adverse events, testing, storage, labeling, intracenter transport of product, and emergency care of the donor. Center must also have a written procedure(s) for addressing deviations from SOPs and practice guidelines, and for performing corrective actions.

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**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. 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.

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