

# **NATIONAL MARROW DONOR PROGRAM® DONOR CENTER PARTICIPATION CRITERIA**

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

Donor Centers that perform donor recruitment activities in addition to donor management activities must comply with Recruitment Group Participation Criteria and the Participation Agreement Rider for Recruitment Activities.

## **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 a designated site for donor management activities, including a private space for donor counseling sessions and a secure environment for confidential record storage.
3. Center must have adequate and appropriate resources to support its donor management activities.
4. U.S. centers must have a Federalwide Assurance (FWA) filed with the Office for Human Research Protection (OHRP).
5. Center must have computers with access to the Internet, and operate the NMDP-specified web-based application or a mutually acceptable alternative application.

## **PERSONNEL**

6. Center must have a Medical Director who:
  - a. Is a licensed physician;
  - b. Has at least one year of experience in donor management and regulatory compliance;
  - c. Has training and experience in evaluating donor suitability and eligibility, and supervising donor management;
  - d. Has training in human subject protection; and
  - e. Participates annually in educational activities in the field of hematopoietic cell collection or transplantation (at least one CME credit hour or non-U.S. equivalent per year).
7. Center Medical Director is responsible for:
  - a. Interpretation and application of NMDP Participation Requirements;
  - b. Protecting the safety of the donor, and identifying conditions in the donor that may be transmissible by transfusion or transplantation;

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- c. Timely interpretation of NMDP medical eligibility criteria for donor participation; and
  - d. Oversight of NMDP research activity according to applicable protocol(s).
8. Center must provide daily and emergency coverage by a designated staff coordinator(s) who is proficient in English, and sufficient in number to meet the needs of the center's activities.
  9. Center must arrange for a licensed physician or appropriately-licensed mid-level practitioner to perform and/or evaluate a complete medical history, physician examination, and laboratory evaluation of the donor to determine if the donor is an acceptable candidate for 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 Apheresis or Collection Center Medical Director.
  10. Center personnel (staff and volunteers) must comply with NMDP training requirements, including but not limited to confidentiality and courier training.
  11. Center must document staff and volunteer training, continuing education, and continued competency for relevant skills.

**SUPPORT SERVICES**

12. Center must offer donor advocacy services to all potential donors and donors.
13. Center must have financial and accounting support available.
14. Center must have prompt technical support available for information technology systems.
15. Center must use NMDP-designated facilities, or 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. Infectious disease marker (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-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 accredited by the American Society for Histocompatibility and Immunogenetics (ASHI)- or the European Federation for Immunogenetics (EFI)-accredited for HLA-typing required by the NMDP
  - d. Blood bank licensed or registered by the FDA (or non-U.S. equivalent) for the collection of autologous blood units

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**POLICIES AND PROCEDURES**

16. Center must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP).
17. Center must maintain standard operating procedures (SOPs) for the management of donors, to include:
  - a. Contacting, testing, and screening donors;
  - c. Accessing donor advocacy services; and
  - d. Arranging product donation
18. Center must participate in the NMDP/CIBMTR Research Sample protocol and the Research Database protocol.
19. Center must use NMDP-provided or NMDP-approved education materials and consent forms.
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.

**ADMINISTRATION**

21. Center must comply with NMDP Participation Requirements, which include NMDP Standards, Policies, Procedures, and terms of the Participation Agreement and Rider.
22. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.
23. Center must meet established Continuous Process Improvement (CPI) and Performance Management System criteria.
24. Center must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis.
25. Center must complete and submit NMDP data forms as required.
26. Center must have and follow written Procedures of Interaction (POI) developed in collaboration with NMDP marrow Collection Centers(s) and Apheresis Center(s).
27. Center must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.
28. Center must promptly report to the NMDP any significant changes in personnel facilities, or support services.

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**APPLICANT CENTERS**

Review and acceptance of new NMDP Donor Center applications by the NMDP will be based on whether the center meets the minimum criteria as stated above, whether the center can demonstrate a need for its participation, and if the establishment of the center meets the business needs of the NMDP. At the time of initial application, applicant center must meet the following additional criteria:

29. Center must be an established Institution and must have demonstrated experience in management of blood, stem cell, or bone marrow donors, including education, counseling, confidentiality, and medical screening.
30. Center must have demonstrated experience working with clinical research trials, and services or products regulated by the U.S. FDA.
31. Center must provide their donor management business model and its added value to the NMDP.
32. Center must have an HLA-A, -B and -DRB1-typed file of at least 10,000 donors that it would manage.

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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.*