NATIONAL MARROW DONOR PROGRAM®
DONOR CENTER PARTICIPATION CRITERIA

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, guidelines, protocols, 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 Center Participation Criteria and the Participation Agreement Rider for Recruitment Activities.

In this document, "registry member" and "donor" both refer to volunteers who are listed on the Be The Match ® Registry. *Registry member* applies to volunteers who have not donated, and *donor* applies to volunteers who have donated a hematopoietic cell product.

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;

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 are 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 registry members 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 applicable 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)

c. Laboratory(ies) that perform eligibility testing for evidence of infection due to relevant communicable disease agents must use donor screening tests that the

U.S. Food and Drug Administration (FDA) has approved, licensed, or cleared for such use and testing must be performed in accordance with the manufacturer's instructions.

d. Laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing required by the NMDP

e. Blood bank licensed or registered by the FDA (or non-U.S. equivalent) for the collection of autologous blood units

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;

    b. Accessing donor advocacy services; and

    c. 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 (registry members), donors, patients, and recipients.

21. Center must maintain relevant records to ensure the identification and traceability/trackability of each registry member, donor and cellular therapy product and all related samples

    a. from their initial source, through each processing and testing step to their final disposition; and

    b. from final disposition, though each processing and testing step back to the initial source.

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

23. Center must have processes and procedures in place 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

ADMINISTRATION

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

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:

32. 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.
33. Center must have demonstrated experience working with clinical research trials, and services or products regulated by the FDA.
34. Center must provide their donor management business model and its added value to the NMDP.
35. Center must have an HLA-A, -B and -DRB1-typed file of at least 10,000 donors that it would manage.

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