NATIONAL MARROW DONOR PROGRAM® (NMDP)/BE THE MATCH®
U.S. DONOR CENTER PARTICIPATION CRITERIA

This document refers to criteria required by National Marrow Donor Program (NMDP)/Be The Match (referred to as NMDP throughout the document). ~~NMDP may, in its discretion, approve deviations from these criteria on a case-by-case basis upon demonstration by the center of extenuating circumstances.~~

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 and support laboratories.

Donor centers performing 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 have experience in the management of blood, stem cell, and bone marrow donors~~apheresis or marrow donors~~, including education, counseling, ~~confidentiality issues and~~ medical screening, and maintenance of confidentiality.

2. Center must have adequate staff, resources, space, equipment, and supplies to perform and manage donor management activities, including a private space for donor counseling sessions.

3. Center must have secure record storage.

4. Centers participating in human subject research must hold a Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP).

5. Center must be registered with the Food and Drug Administration (FDA) as a manufacturer of human cells, tissues, and cellular and tissue-based products (HCT/Ps), if appropriate.

6. Center must have computers with access to the internet, and operate the NMDP-specified web-based application or a mutually acceptable alternative application.

PERSONNEL

7. Center must designate an NMDP medical director who is a licensed physician qualified by training and experience to evaluate and determine donor medical suitability, supervise donor management, and:

   a. Has at least one year of experience in donor management and regulatory compliance.

   b. Has training in human subject protection.

   c. Participates annually in educational activities related to the field of hematopoietic cell

collection or transplantation (at least one CME credit hour per year).

d. Assures physician designees are trained and qualified; any responsibility(ies) of the center medical director may be fulfilled by a designated center physician.

8. Donor center medical director (or designee) is responsible for:

   a. Interpretation and application of NMDP participation requirements.

   b. Protection of the donor's safety including identification of conditions in the donor that may be transmissible by transfusion or transplantation.

   c. Interpretation of NMDP eligibility criteria.

   d. Oversight of NMDP research activity according to applicable protocol(s).

9. Center must provide daily and emergency coverage by designated staff coordinator(s) who are proficient in English, and sufficient in number to meet the needs of the center's activities.

10. Center must arrange for an examining practitioner to perform and/or evaluate a complete medical history, physician examination, and laboratory evaluation of the donor before proceeding with donation. For purposes of this criterion, an examining practitioner is defined as a licensed physician, physician's assistant, or nurse practitioner consistent with applicable law. The evaluation and test results must be reviewed and approved by the donor center medical director (or designee) and apheresis or collection center medical director/physician designee.

11. Center personnel (staff and volunteers) must comply with NMDP training requirements.

12. Center must document staff and volunteer training, continuing education, and continued competency for relevant skills.

13. All donor center workup staff must complete training in human subject protection if center uses the NMDP IRB.

14. All donor center workup staff and medical directors must submit the *Significant Financial Interest Disclosure Form* annually if center uses the NMDP IRB.

SUPPORT SERVICES

15. Center must offer donor advocacy services to all registry members and donors.

16. Center must have financial and accounting support available.

17. Center must have prompt technical and operational support for information systems management.

18. Center must use NMDP-designated facilities, or facilities that are licensed, certified, or accredited in accordance with applicable governmental laws and regulations. Additional requirements include:

a. Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) for tests required by NMDP.

b. Laboratory(ies) used for infectious disease marker (IDM) testing must be an NMDP-contracted laboratory.

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

d. Blood bank(s) licensed or registered by the FDA for the collection of autologous blood units.

POLICIES AND PROCEDURES

19. Center must have and follow written agreements [e.g., Universal Procedures of Interaction (UPOI)] defining roles and responsibilities developed in collaboration with participating bone marrow collection center(s) and apheresis collection center(s).

20. Center must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP).

21. 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.

    c. Arranging product donation.

22. Center must participate in the NMDP/CIBMTR research sample protocol and the research database protocol.

23. Center must use NMDP-provided or NMDP-approved education materials and consent forms.

24. Center must maintain a system of strict confidentiality of records that meets or exceeds NMDP requirements to protect the privacy of potential donors (registry members), donors, and patients.

25. Center must maintain relevant records in accordance with NMDP Standards 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.

    b. From final disposition through each processing and testing step back to the initial source.

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

27. Center must have processes and procedures in place to promptly identify, process, report, and prevent, if applicable, the following per NMDP requirements:

    a. Adverse Events
    b. Deviations

c. Product Complaints
d. Nonconforming products, materials, or services
e. Corrective actions and preventive actions (CAPA)

ADMINISTRATION

28. Center must comply with NMDP participation requirements, which include NMDP Standards, policies, procedures, guidelines, protocols, and terms of the participation agreement and rider.

29. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.

30. Center must meet established continuous process improvement (CPI) and performance management system criteria.

31. Center must provide documentation that it continues to meet NMDP participation requirements on an annual basis.

32. Center must complete and submit NMDP data forms as required.

33. Center must maintain adequate professional and general liability insurance coverage, as required in the participation agreement.

34. Center must promptly report to the NMDP any significant changes in personnel (including but not limited to medical director and coordinator), facilities, accreditations, FDA registration, or support services. Any change to FDA registration must be reported to the NMDP no later than 15 days after receipt of notice.

APPLICANT CENTER

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:

35. Center must be an established institution and must have demonstrated experience in the management of blood, stem cell, and bone marrow donors, including education, counseling, ~~confidentiality, and~~ medical screening, and maintenance of confidentiality.

36. Center must have demonstrated experience working with clinical research trials, and services or products regulated by the FDA.

37. Center must provide their donor management business model and its added value to the NMDP.

38. 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 under extenuating circumstances.