This document refers to criteria required by National Marrow Donor Program (NMDP)/Be The Match (referred to as NMDP throughout the remainder of 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 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 and support laboratories.

**FACILITY CHARACTERISTICS**

1. Center must be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS).
2. Center must have adequate staff, resources, space, equipment, and supplies, to perform and manage collection-related activities.
3. Centers must have secure record storage.

**PERSONNEL AND MARMOW COLLECTION TEAM**

4. Center must designate a medical director who is a licensed physician and:
   a. Has post-doctoral training in hematopoietic cell collection or transplantation.
   b. Has at least one year experience in the HPC(M) collection procedure.
   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 that physician designees are trained and qualified; any responsibility(ies) of the center medical director may be fulfilled by a designated center physician.
5. The center medical director (or designee) is responsible for:
   a. Protecting the safety of the donor and product(s).
   b. Interpretation and application of NMDP participation requirements.
6. Center medical director, physician designee, or examining practitioner must perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for HPC(M) collection including evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation. 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 collection center medical director/physician designee and the donor center medical director or designee.
7. The collecting physician must:
   a. Be a licensed physician in the state where collection occurs.
   b. Have performed at least ten prior collections of HPC(M) for transplantation with at least
three collections in the previous three years.

c. Be present for the duration of the HPC(M) collection.

d. Participate annually in educational activities related to the field of hematopoietic cell collection or transplantation (at least one CME credit hour per year).

8. Center must have an experienced team that has collected HPC(M) at the center at least three times in the past three years.

a. Any person assisting in the HPC(M) aspiration (physician, physician assistant, nurse, technician) must have documented, adequate training in HPC(M) collections for transplantation.

9. Center must administer anesthesia under supervision of a licensed, board certified anesthesiologist or certified nurse anesthetist.

10. Physician is responsible for determining the donor’s health is appropriate for discharge.

a. Donor shall be admitted and discharged from the collection center the same day, unless the medical status precludes it.

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

12. Center personnel must comply with NMDP training requirements.

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

**Support Services**

14. Center must have a surgical operating room and a medical intensive care unit.

15. 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.

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

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

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

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

18. Center must provide the donor with post-donation care instructions that include appropriate contact names and phone numbers at time of discharge.
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 donor center(s).

20. Center should have the capability to collect and store autologous red cell units prior to HPC(M) collection if necessary.
   a. Center must verify that if autologous units have been collected, the units are available prior to the HPC(M) collection.

21. 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.

22. Center must maintain written standard operating procedures (SOPs) to address at least the following:
   a. Donor evaluation
   b. Product collection (collected marrow volume must not exceed 20 ml/kg donor body weight)
   c. Management and reporting of adverse events
   d. Testing
   e. Storage (materials, components, and final product are stored in environmental monitored areas)
   f. Product final labeling (center must adopt NMDP SOPs)
   g. Intra-center transport of product
   h. Product distribution and release
   i. Emergency care for the donor
   j. Internal quality auditing
   k. Corrective actions and preventive actions (CAPA)

23. Center must maintain records, in accordance with NMDP Standards, to ensure the identification and traceability/trackability of each donor and all related cellular therapy products and all related 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 a minimum 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

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

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

APPLICANT CENTER

Review and acceptance of NMDP collection center applications by the NMDP will be based on whether the center meets the minimum criteria as stated above, 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:

33. Applicant center must submit a collection log documenting that center has performed at least three HPC(M) collections in the past three years.

34. Applicant center’s physician performing or supervising the collection must have performed at least ten prior collections of HPC(M) for transplantation with at least three collections in the previous three years.