National Marrow Donor Program®/Be The Match®
International Collection Center Participation Criteria

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

The NMDP has established these criteria to address minimum required elements for participation in the NMDP network as an international product collection center. Through an application process, applicants must document that these requirements are met. The NMDP has also established standards, policies, procedures, guidelines, and participation agreements that may impose additional requirements for centers.

In this document, “center” refers to a hospital or other institution that collects marrow [HPC(M)] and/or PBSC [HPC(A)] products.

Facility Characteristics

1. Center must be a legal entity or be contained within a legal entity operating within the laws of the country in which the center resides.
2. Center must comply with national and local regulations.
3. Center must have adequate staff, resources, space, equipment and supplies to perform and manage collection related activities.
4. Center must have secure record storage.
5. For HPC(A) collections, center must be 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).

Personnel and Collection Team

6. Center must designate a medical director who is a licensed physician and:
    a. Has at least one year experience in the applicable collection procedure;
    b. Participates annually in educational activities related to the field of hematopoietic cell collection or transplantation;
    c. Assures physician designees are trained and qualified; any responsibility of the center medical director may be fulfilled by a designated center physician.
7. The medical director (or designee) is responsible for:
    a. Protecting the safety of the donor and product(s);
    b. Performing and/or reviewing a complete medical evaluation of the donor to determine whether the donor is an acceptable candidate for HPC(M) and/or HPC(A) collection, including evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation;
    c. Interpretation and application of NMDP participation requirements.
8. For HPC(A) collections, the collecting physician must:
    a. Have performed or supervised at least ten (10) cellular product apheresis collection procedures within the last three years;
    b. Be available onsite or by telephone throughout mobilizing agent administration, for the duration of each collection, and follow-up as needed (or appoint a physician designee);

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c. Ensure mobilization agents are administered under the supervision of a licensed physician experienced in their administration and in the management of complications in persons receiving these agents.

9. For HPC(M) collections, the collecting physician must:
   a. Have performed at least ten (10) prior marrow collections for transplantation with at least three (3) collections in the previous three years;
   b. Be present for the duration of each collection;
   c. Be responsible for determining the donor's health is appropriate for discharge.
10. A licensed physician qualified by training and experience must place and monitor removal of any required central venous catheters.
11. For HPC(M) collections, anesthesia must be administered under supervision of a licensed, certified, or accredited anesthesiologist in accordance with its country's requirements.
12. Center must document the qualifications, responsibilities, training, continuing education, and continued competency for relevant skills for its staff.
    a. Center shall have an experienced team who has performed at least three HPC(M) collections in the past three years at the center.
    b. Center shall have an experienced team who has performed at least three collections of mononuclear cells by apheresis in the past year.
13. Center must provide daily and emergency coverage by designated coordinator(s) who are proficient in English to provide prompt response to requests.

Support Services

14. The clinical laboratories utilized by the center (hematology, blood bank, microbiology, chemistry) must be licensed, certified, or accredited in accordance with its country's requirements.
15. Center must be able to ship donor blood samples to the U.S. for timely arrival. Per U.S. FDA regulations, workup infectious disease marker testing must be performed at a CLIA certified lab in the U.S. for all U.S. patients.
16. Collection center must ensure the identity, safety, and privacy of the donor.
17. Centers performing marrow collections [HPC(M)] must:
    a. Have a surgical operating room and medical intensive care unit available at the facility;
    b. Have irradiated and leukoreduced blood components available in the event that the use of allogeneic blood cannot be avoided;
    c. Verify that if autologous units have been collected, the units are available prior to the HPC(M) collection. Autologous blood must be collected at a center that fulfills national guidelines in that country.
    d. Have the ability to store autologous units prior to HPC(M) collection.

Policies and Procedures

18. Center must maintain a system of strict confidentiality of records that meets NMDP requirements to protect the privacy of potential donors (registry members), donors, patients, and recipients. This must include a designated site for the management of collection activities.

19. Center must have a quality assurance program designed at 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
20. Center must maintain and retain relevant records per P00143, *NMDP/Be The Match® Network Participating Centers Record Retention Policy* 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.
21. Center must have written policies and procedures in place to ensure the identity, quality, and quantity of the collected cells. These must include policies for prompt transmission of results and completion of NMDP data forms regarding characteristics of the collected product.
22. Center must promptly report to the NMDP any significant changes in personnel (including, but not limited to, medical director or coordinator), facilities, accreditation status, FDA registration [for HPC(A) collections only], or support services.
23. Cellular product complaints or serious adverse events (SAE) impacting the donor, and hence potentially the patient's health, must be identified, documented, investigated, and remedial and/or corrective action taken by the collection center. The event must be reported to the NMDP.
24. Center must cooperate with any product or adverse event investigation conducted by the NMDP.
25. Product packaging and labeling must comply with national and international regulations.
26. Center must have appropriate policies and procedures to protect the health and safety of the donor if a donor is subjected to a medical intervention (e.g., administration of mobilizing agent) as part of the product collection process.
27. Centers performing HPC(A) collections must have a written policy on peripheral venous assessment and placement of central venous catheters.
    a. The written policy must state that central venous catheters must only be used when peripheral venous access:
        i. Is not deemed feasible after skilled assessment,
        ii. Cannot be obtained, or
        iii. Has failed
    b. The policy must also state that placement of central venous catheters requires written justification.
    c. Adequacy of line placement must be verified prior to use.
27. Center must have and follow written agreements defining roles and responsibilities developed in collaboration with participating donor centers.

Administration

28. Center must comply with applicable NMDP Standards when working with the NMDP.
29. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.
30. Center must maintain adequate professional and general liability insurance coverage.
31. Center must provide documentation that it continues to meet NMDP participation requirements on an annual basis.