NATIONAL MARROW DONOR PROGRAM®/BE THE MATCH®
INTERNATIONAL COLLECTION FACILITY PARTICIPATION CRITERIA

National Marrow Donor Program / Be The Match® (NMDP) has established Participation Criteria to address minimum required elements for participation in the NMDP Network as an international collection center. Applicants must document, through an application process, that these requirements are met.

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

PERSONNEL AND COLLECTION TEAM

1. Center must designate a Medical Director who is a licensed physician and:
    a. Has at least one year experience in the appropriate collection procedure;
    b. Has post-doctoral training in hematopoietic cell (HPC) collection or transplantation;
    c. Participates annually in educational activities related to the field of hematopoietic cell collection or transplantation;
    d. Assures that physician designees are trained and qualified; any responsibility of the center medical director may be fulfilled by a designated center physician.
2. The medical director (or physician designee) is responsible for protecting the safety of the donor and product(s), and for identifying conditions in the donor that may be transmissible by transfusion or transplantation.

    For centers performing apheresis collections [HPC(A)]:

    a. The physician must:
        i. Have performed or supervised at least ten cellular product apheresis collection procedures within the last three years;
        ii. Participate annually in educational activities related to the field of hematopoietic cell collection or transplantation.
    b. A licensed physician qualified by training and experience must place any required central venous catheters

    For centers performing marrow collections [HPC(M)]:

    a. The physician must:
        i. Have performed at least 10 prior collections of HPC(M) for transplantation with at least three collections in the previous three years;
        ii. Participate annually in educational activities related to the field of hematopoietic cell collection or transplantation;
        iii. Maintain documented operating room privileges at the collection center;
        iv. Be present for the duration of the marrow collection.
    b. When required, center must administer anesthesia under supervision of a licensed, certified or accredited anesthesiologist, in accordance with its country’s requirements.
3. Center must document the qualifications, responsibilities, training, continuing education, and continued competency for relevant skills for its staff.

4. Center must provide daily and emergency coverage by designated coordinator(s) who are proficient in English to provide prompt response to requests.

SUPPORT SERVICES

5. 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.
6. Collection facility must provide written documentation of the characteristics of the collected product (including cell counts) with the product, according to applicable guidelines.
7. Collection facility must ensure the identity, safety, and privacy of the donor.
8. Centers performing marrow collections [HPC(M)] must have a surgical operating room and medical intensive care unit available at this hospital.

POLICIES AND PROCEDURES

9. 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 and a secure environment for confidential record storage.
10. 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. Complaints
    d. Nonconforming products, materials or services
    e. Corrective actions and preventive actions
11. Center must maintain and retain relevant 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.
12. Collection facility must have written policies and procedures in place to ensure the identity, quality and quantity of the collected cells. These must include policies for communication between the requesting registry, collection facility, and cell processing unit regarding the number of cells required and the number of cells able to be obtained.
13. 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, or support services.
14. 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 facility. The event must be reported to the WMDA's SEAR/SPEAR centralized database, via the donor's managing registry.
15. Collection facility must cooperate with any product or adverse event investigation conducted by the NMDP.

16. Cells must be transported in a timely and reliable fashion to meet transplant center requirements for the quality and quantity of the cell product. Packaging must comply with national and international regulations. Policies and procedures documenting the transport process must be stipulated.
17. Collection facility must have appropriate policies and procedures to protect the health and safety of the donor and of the recipient if a donor is subjected to a medical intervention (e.g. administration of GCSF) as part of the product collection process.
    a. For centers performing HPC(A) collections, these policies should include the procedure to be followed in case of failed mobilization
18. Centers performing HPC(A) collections must have a written policy on the 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.

ADMINISTRATION

19. Center must comply with applicable NMDP Standards when working with the NMDP.
20. Center must comply with applicable World Marrow Donor Association (WMDA) Standards.

FACILITY CHARACTERISTICS

21. 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) (Apheresis Centers).
22. 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.
23. Center must comply with national and local regulations.
24. Center must have adequate staff, resources, space, equipment and supplies to perform and manage collection related storage.
25. Center must have secure record storage.