NMDP
International Collection Center Participation Criteria

This document refers to criteria required by NMDP. At NMDP's discretion deviations from the following criteria may be approved on a case-by-case basis upon demonstration of extenuating circumstances by the center.

NMDP has established the following 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 the following requirements are met. 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 peripheral blood stem cell (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 hematopoietic progenitor cell (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 meets the following requirements:

    a. Has at least one year experience in the applicable collection procedure.

    b. Participates annually in educational activities related to the field of HPC collection or transplantation.

    c. Assures physician designees are trained and qualified.

        i. 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 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).

   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 prior marrow collections for transplantation with at least three 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 their country's requirements.

12. Center must document staff's qualifications, responsibilities, training, continuing education, and continued competency for relevant skills.

    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 their 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 Clinical Laboratory Improvement Amendments (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 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 meet the minimum requirements of having a quality assurance program (per NMDP requirements) designed to promptly identify, process, report, and prevent (if applicable) the following:

    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 according to PL-00109, *NMDP Network Participating Centers Record Retention Policy* to ensure the identification and traceability/trackability of the following:

    a. Donor

    b. All donor-related cellular therapy products

    c. 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.

    a. 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 NMDP any significant changes including:

    a. Personnel (including, but not limited to, medical director or coordinator)

    b. Facilities

    c. Accreditation status

    d. FDA registration [for HPC(A) collections only]

    e. Support services

23. Cellular product complaints or serious adverse events (SAE) impacting the donor (potentially the patient's health) must be identified, documented, and investigated.

    a. Remedial and/or corrective action must be taken by the collection center.

    b. The event must be reported to the NMDP.

24. Center must cooperate with any product or adverse event investigation conducted by 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

iii. Has failed

b. The policy must also state that placement of central venous catheters requires written justification.

c. The adequacy of line placement must be verified prior to use.

28. Center must have and follow written agreements defining roles and responsibilities developed in collaboration with participating donor centers.

Administration

29. Center must comply with applicable NMDP standards when working with NMDP.

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

31. Center must maintain adequate professional and general liability insurance coverage.

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