

NATIONAL MARROW DONOR PROGRAM/Be The Match®
PARTICIPATION CRITERIA FOR
INTERNATIONAL DONOR CENTERS AND REGISTRIES

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

In this document, “center” refers to either a donor registry (and any of its affiliated centers), or a non-U.S. (international) donor center managing adult donors and the processes for obtaining products from adult donors. A separate set of criteria is in place for cord blood banks that are part of a registry.

CENTER 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 be a member of the World Marrow Donor Association (WMDA).
3. Center must comply with applicable WMDA Standards and national and local regulations.
4. Center must comply with applicable NMDP Standards when working with the NMDP.
5. Center must be able to provide donor blood samples to the United States for testing, in compliance with international shipping standards.
6. Center must have at least 1,000 volunteer donors typed for HLA-A, B and DRB1.
7. Center should be actively recruiting new donors.
8. Center must have defined criteria for histocompatibility matching, with searches performed and reported electronically.
9. Center or any affiliated centers performing applicable donor management activities 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) and provide the NMDP with a copy of its establishment registration form (Form 3356) if/when requested.
10. Center must have adequate staff, resources, space, equipment, communication links, and supplies to support its donor management activities, including a private space for donor counseling sessions to maintain confidentiality.
11. Center must have secure record storage, either electronic or paper form, to ensure confidentiality and allow for traceability.
12. Centers participating in human subject research must follow country specific regulations and policies, and have a designated Institutional Review Board (IRB) or similar entity.

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PERSONNEL

13. Center must have a director or key personnel with demonstrated experience in program administration in a health care setting. At least one of the center personnel must be a physician who is licensed to practice medicine in the respective country.

The director or key center personnel must:

- a. Have relevant experience in HPC donor management and regulatory compliance.
- b. Have expertise in human histocompatibility and hematopoietic stem cell transplantation as documented by relevant education and experience.
- c. Possess knowledge of transplant center, donor center, product collection center and registry protocols in their own country and abroad.
- d. Have training in human subject protection, if center participates in research studies.

The physician associated with the center is responsible for the protection of the donor's safety to proceed with donation and identify conditions in the donor that may be transmissible by transfusions or transplantation.

14. Center must document the qualifications, responsibilities, training, continuing education, and continued competency for relevant skills for its staff.
15. Center must provide daily and emergency coverage by designated coordinator(s) who are proficient in English to provide prompt response to requests. The staff must be sufficient in number to meet the needs of the center's activities.

SUPPORT SERVICES

16. Center must have prompt technical and operational support for information systems management.
17. Center must have financial and accounting support available.
18. Center must use facilities that are licensed, certified, or accredited in accordance with country-specific laws and regulations:
- a. Laboratories performing clinical testing must meet standards established by the government, and/or be certified/accredited by appropriate national competent authority.
 - b. Laboratories performing HLA typing should be accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP).

POLICIES AND PROCEDURES

19. Center must maintain written policies and protocols for all processes performed at the center, as well as a process for regular review of these documents. The center's

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Standard Operating Procedures (SOPs) detailing procedures for donor management must include:

- a. Contacting, consenting, testing, and screening donors.
 - b. Educating donors about the process and risks of donating.
 - c. Arranging product donation.
20. Center must maintain relevant records to ensure the identification and traceability of each donor 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.
21. Center must have a system of quality management to assess, ensure and improve the quality of its operations.
- a. Center must have established processes to monitor and ensure the accuracy and completeness of the data listed in the donor database, including a system to ensure the quality of HLA typing results.
 - b. Center must have established processes and procedures to promptly identify, investigate, report, and prevent quality incidents and adverse events.
22. Center must maintain a system of strict confidentiality, and abide by NMDP's policies and procedures on confidentiality (P00023), to protect the privacy of donors and patients.

DONOR MANAGEMENT

23. Donors must be willing to donate on behalf of any patient being treated in any part of the world and must not receive payment for donating. Donors must be free to withdraw at any time.
24. Donor recruitment must be performed under the direction of individuals who are experienced in recruitment of donors and in management activities including education, consenting, counseling, confidentiality, and medical screening. Recruitment practices must meet relevant national laws and regulations.
25. Donor records must contain, at a minimum, a unique donor identifier, donor HLA type, age and gender.
26. Donors must be counseled when selected for further tests and when selected as a donor for a specific patient; donors must be fully informed about the process and risks of donating hematopoietic stem cell products.
27. Donor selected for work-up must be screened and tested according to policies that address medical history, physical exam, and laboratory tests in order to determine the donor's fitness to donate.

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- a. Donors must pass all medical screening requirements in accordance to local laws and regulations; examination must be performed or supervised by a physician.
 - b. Medical history evaluation must include questions and/or testing to identify the risk of spread of communicable diseases.
- 28. Donors must provide signed valid informed consent at the time of recruitment and at the time of work-up.
 - 29. Donor identity must be verified, at a minimum, at work-up and at collection, by qualified staff.
 - 30. Center must have a qualified and trained health care professional readily available to assist with routine medical decisions regarding donor care.
 - 31. Center must have policies and procedures for the first year following donation for the follow-up and care of donors for conditions related to the hematopoietic stem cell donation.
 - 32. Center must provide healthcare treatment or insurance for its donors for conditions related to the HPC donation.

COLLECTION FACILITIES

- 33. Collection facilities that collect products for NMDP recipients 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). The center (registry or donor center) is responsible for ensuring that this registration is complete and current, and providing the NMDP with a copy of the establishment registration form (Form 3356) if/when requested.
- 34. Collection facilities used by the center must meet all standards and requirements established by the government or national competent authority. In the absence of national requirements, the center must establish requirements and ensure compliance. Center must have a formal agreement in place with each collection facility and have a process in place to ensure center is compliant with all applicable regulations and requirements.
- 35. Collection facility must ensure the identity, safety and privacy of the donor.
- 36. Collection facility must have a designated site for the management of collection activities and a secure environment for confidential record storage.
- 37. Collection facility and the procurement of HPC must be under the direction of trained and experienced health care professionals.
- 38. 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.

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- a. These policies should include the procedure to be followed in case of failed mobilization.
 - b. The collection facility must have a policy concerning the use of a central venous catheter (CVC) in volunteer donors to assure that a CVC is only used in exceptional circumstances. Those circumstances must be documented.
 - c. The collection facility must have a policy that protects the safety of the volunteer donors with a CVC inserted.
39. 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 transplant center, collection facility, and cell processing unit regarding the number of cells required and the number of cells able to be obtained.
 40. Collection facility must provide written documentation of the characteristics of the collected product (including cell counts) with the product, according to applicable guidelines.
 41. 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.
 42. Collection facility must cooperate with any product or adverse event investigation conducted by the NMDP. The center is responsible for working with the product collection facility to obtain all relevant information to complete NMDP's investigation.
 43. 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.

PATIENT SEARCH MANAGEMENT (IF APPLICABLE) FOR DONOR REGISTRIES

44. The registry must be authorized to request donor searches of the NMDP on behalf of transplant centers it represents. All searches, communications and financial transactions must occur between the NMDP and the registry.
45. Transplant Centers represented by the registry must meet all standards and requirements established by the government or national competent authority. In the absence of national requirements, the registry must establish requirements and ensure compliance. Registry must have a formal agreement in place with each transplant center and have a process in place to ensure each center is compliant with all applicable regulations and requirements.
46. The registry must inform its represented transplant centers of their obligation to submit post-transplant outcome data to the European Group for Blood and Marrow Transplantation (EBMT) or Center for International Blood and Marrow Transplant (CIBMTR) for recipients who received a U.S. donor product or a U.S. cord blood unit.

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ADMINISTRATION

47. Center must submit a program description outlining experience and information about its donor management and patient search management (if applicable) practices and procedures.
48. Center must promptly report to the NMDP any significant changes in operations, accreditations, FDA registration, or support services (including donor management centers, product collection centers, laboratories, etc), no later than 15 days after center receives notice of change.
49. Center must notify the NMDP of any FDA, local or national enforcement action.
50. Center must sign an Agreement with the NMDP that outlines the terms and conditions of the relationship.

These criteria set forth only the basic guidelines for centers working with the NMDP and do not set forth all that may be required of an individual, facility or organization to conform to local or national laws or regulations, or standards of care prevailing in the relevant community. Each individual, facility, or organization must determine and follow any additional laws, regulations, practices and procedures that apply in their particular community. The NMDP disclaims all representation or warranties, expressed or implied that compliance with these criteria will fulfill all applicable national or local laws or regulations, or the standard of care prevailing in the relevant community.

NMDP may, in its discretion, approve deviations from these criteria on a case-by-case basis upon demonstration by the center of extenuating circumstances.