NATIONAL MARROW DONOR PROGRAM®
TRANSPLANT CENTER PARTICIPATION CRITERIA

National Marrow Donor Program® (NMDP) has established Transplant 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.

In this document, the terms “patient” and “recipient” both refer to the spectrum of individuals who are potential candidates for hematopoietic cell transplantation to individuals who have received a hematopoietic cell product.

FACILITY CHARACTERISTICS

1. Center must be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS), or non-US equivalent.
2. Center must use a designated inpatient unit that minimizes microbial contamination.
3. Center must have a designated site for management of search activities.
4. Center must use a designated area for outpatient evaluation and treatment that reduces the risk of transmission of infectious agents and is available 24 hours per day, seven days per week.
5. A program with multiple patient care units that requests to be recognized as a single NMDP center must demonstrate functional unity through shared elements that include:
   a. A medical director who has NMDP responsibilities for all units and serves as the single point of contact for the NMDP on clinical matters
   b. Standard operating procedures and policies
   c. Staff training programs

   If the patient care units are located in more than one institution:
   a. At least the primary institution must satisfy all Transplant Center Participation Criteria, and
   b. The secondary institution(s) must demonstrate evidence of functional unity with the primary institution for at least the past year, and must have performed allogeneic transplants for at least five different patients in the past year.
6. Center must have adequate resources to support its NMDP activities.
7. U.S. centers must have a current Federalwide Assurance (FWA) filed with the Office for Human Research Protection (OHRP). Non-U.S. centers must provide evidence of compliance with Independent Ethics Committees (IEC) within their country.

PERSONNEL AND TRANSPLANT TEAM

8. Center must designate an NMDP medical director who:
   a. Is a licensed physician;
   b. Is board certified (or non-U.S. specialist certification equivalent) in one or more of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology. Non-board certified physicians who completed medical training prior to 1985 may serve as the NMDP Medical Director if they have documented experience in the field of hematopoietic progenitor cell transplantation extending over ten years;
   c. Is responsible for search management activities and protecting the safety of the recipient;
   d. Has had at least two years experience, within the past five years, as an attending physician responsible for clinical management of allogeneic transplant recipients in the inpatient and outpatient settings; and
   e. Participates annually in educational activities related to the field of hematopoietic cell transplantation (at least one CME credit hour or non-U.S. equivalent per year).
9. Center must have at least two attending physicians (including the NMDP medical director) who:
   a. Are licensed physicians;
   b. Are qualified by training and experience in allogeneic hematopoietic cell transplantation. Adequate clinical training in allogeneic cell transplant is defined as a minimum of one year experience in the management of transplant recipients in both the inpatient and outpatient settings;
   c. Provide 12-month coverage for both the inpatient unit and outpatient clinic;
   d. Should be board certified (or non-U.S. specialist equivalent) in one or more of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology; and
   e. Participate annually in educational activities related to the field of hematopoietic cell transplantation (at least one CME credit hour or non-U.S. equivalent per year).
10. Center must use an experienced team that has performed allogeneic transplants for at least 10 different patients within the past year. Center must demonstrate that allogeneic recipients achieved survival rates acceptable to the NMDP. A center that performed fewer than 10 allogeneic transplants per year for the past 24 months may qualify as a Low Volume Transplant Center, as described in criterion #46.
11. Centers performing pediatric transplants must use a transplant team trained in the management of pediatric patients.
12. Center must provide daily and emergency coverage by designated transplant coordinator(s), who are proficient in English, and sufficient in number to meet the needs of the center's activities.

13. Center must have nurses qualified by training and experience in the care of transplant recipients, with the capacity for 1:1 nurse-to-inpatient ratio for acutely ill patients.
14. Center must have sufficient data management personnel to comply with the Center for International Blood and Marrow Transplant Research (CIBMTR) and NMDP data submission requirements.
15. Center personnel must comply with NMDP training requirements, including but not limited to confidentiality and courier training.
16. Center must document staff and volunteer training, continuing education, and continued competency for relevant skills.

SUPPORT SERVICES

17. Center must use facilities that are licensed, certified, or accredited in accordance with applicable U.S. federal and state laws and regulations (or non-U.S. equivalent for non-U.S. centers). Additional requirements include:
    a. Laboratory(ies) certified by Centers for Medicare & Medicaid Services (CMS) (or non-U.S. equivalent) for clinical laboratory tests required by the NMDP.
    b. Laboratory(ies) accredited by the American Society of Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) for HLA typing required by NMDP. The laboratory designated by the transplant center is responsible for the final HLA typing of the patient and donor.
    c. Experienced hematopoietic cell-processing laboratory that is registered with the U.S. Food and Drug Administration (FDA) as a manufacturer of human cells, tissues, and other cellular and tissue-based products (HCT/P). (U.S. Centers only)
    d. Laboratory that can detect CMV infection by quantitative PCR, viral culture, antibody tests or equivalent and provide results within 72 hours.
    e. Transfusion service that provides 24-hour blood component support for transplant patients, including irradiated blood components and components suitable for CMV-negative recipients.
18. Center must use person(s) qualified by training and experience in human histocompatibility testing to assist in the selection of unrelated hematopoietic cells or donors.
19. Center must have experienced physicians who provide consultative services in at least the following disciplines: surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious diseases, cardiology, pathology, psychiatry, and, if applicable, radiation therapy.
20. Center must have sufficient staff from at least the following services: pharmacy, dentistry, dietary, radiology, respiratory therapy, social services and physical therapy.
21. Center must have prompt technical support available for information technology systems.

POLICIES AND PROCEDURES

22. Center must maintain written policies and/or procedures to address at least the following:
    a. Donor or cord blood unit selection;
    b. Financial approval;
    c. Infection prevention and control;
    d. Processing ABO incompatible hematopoietic cell products to reduce the risk of hemolysis;
    e. Hematopoietic cell product infusion;
    f. Blood component transfusion to include transfusion of blood components when the donor and recipient are ABO mismatched; and
    g. Education of the patient pre- and post-transplant.
23. Each recipient of hematopoietic cells from the NMDP must be enrolled in a clinical research protocol which is approved by the center's institutional review board (IRB) or treated according to a written clinical practice guideline.
24. Center must maintain written clinical practice guidelines to address at least the following:
    a. Criteria for patient eligibility;
    b. Patient evaluations;
    c. Preparative regimens for transplantation;
    d. Prevention and treatment of graft-versus-host disease;
    e. CMV prophylaxis, surveillance and treatment; and
    f. Post-transplant care
25. 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 reactions;
    b. Deviations;
    c. Complaints; and
    d. Nonconforming products, materials, or services.
26. Center must maintain relevant records to ensure the identification and traceability/trackability of each donor and cellular therapy product and all related samples
    a. from their initial source, through each processing and testing step to their final disposition; and
    b. from final disposition, through each processing and testing step back to the initial source.
27. Center must retain records in accordance with NMDP Standards.

28. Center must participate in the NMDP/CIBMTR Research Sample protocol and the Research Database protocol.

29. Center must maintain a system of strict confidentiality that meets or exceeds NMDP requirements for the protection of privacy of potential donors, donors, patients, and recipients.

PATIENT ADVOCACY

30. Center must communicate appropriate information about the progress of a search to patients, physicians, and other authorized individuals.

31. If a compatible donor or cord blood unit meeting the criteria of the center is not found, the patient must be informed of other options including:

    a. Referral to other NMDP Network Transplant Centers whose criteria for unrelated and related transplants may be different

    b. Ongoing NMDP search efforts

32. Center must have a patient advocate who is familiar with the center's transplant program and issues of unrelated hematopoietic cell transplantation, but is not a member of the transplant team. The center may designate Be The Match Patient Services as their patient advocate.

33. U.S. centers must provide required information for the NMDP Transplant Center Directory on an annual basis.

ADMINISTRATIVE

34. Center must comply with NMDP participation requirements, which include NMDP Standards, policies, procedures, guidelines, protocols, and terms of the Participation Agreement.

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

36. Center must meet established Continuous Process Improvement (CPI) criteria.

37. Center must provide documentation that it continues to meet NMDP Participation Requirements on an annual basis.

38. Center must have readily available access to the Internet through which search results, daily reports, vital information, transplant dates, and data are exchanged with the NMDP.

39. Center must complete and submit NMDP and CIBMTR data forms as required.

40. Center must assume financial responsibility for services requested by the center and rendered by the NMDP.

41. Center must maintain adequate professional and general liability insurance coverage, as required in the Participation Agreement.

42. Center must promptly report to the NMDP any significant changes in personnel, facilities, accreditations, or support services.

APPLICANT CENTERS

At the time of initial application, applicant center must meet the following additional criteria:

43. Applicant center must have performed primary allogeneic transplants for at least 10 different patients per year during the previous 24 months or primary allogeneic transplants for 20 different patients in the last 12 months to qualify as a Transplant Center. Applicant centers that perform allogeneic transplants for fewer than ten different patients per year are eligible to apply as a Low Volume Transplant Center (see Low Volume Transplant Center definition below).

44. Applicant center must submit a "Hematopoietic Stem Cell Transplant History" Form documenting all allogeneic transplants for the previous 24 months, to include the day +100 status for each patient. Experience must demonstrate that applicant center achieved appropriate allogeneic recipient survival rates.

45. Applicant center's transplant team (including at least one attending physician and a majority of the inpatient and outpatient nurses) must have performed allogeneic transplants at the center for at least the past 12 months.

LOW VOLUME TRANSPLANT CENTERS

46. Applicant or existing NMDP Network Transplant Centers that performed allogeneic transplants for fewer than 10 different patients per year for the previous 24 months may be eligible to participate as Low Volume Transplant Centers. Low Volume Transplant Centers must demonstrate their ability to provide access to unrelated transplants for patients facing barriers that may not be addressed by current NMDP Network Transplant Centers. Low Volume Transplant Centers receive additional NMDP search support and are assessed added fee(s).

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