NMDP
U.S. Transplant Center Participation Criteria

NMDP has established U.S. Transplant Center Participation Criteria to address the 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 and support laboratories.

If a transplant center holds current Foundation for the Accreditation of Cellular Therapy (FACT) accreditation in allogeneic transplants, proof of accreditation may be provided in lieu of completing an application to verify compliance with the U.S. Transplant Participation Criteria.

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 the Centers for Medicare & Medicaid Services (CMS).

2. Center must use a designated inpatient unit that minimizes the risk of infection.

3. 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.

4. 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 the following:

    a. A medical director (who has NMDP responsibilities for all units and serves as the single point of contact for NMDP on clinical matters)

    b. Standard operating procedures (SOPs) and policies

    c. Staff training programs

5. If the patient care units are in more than one institution the following must be met:

    a. The primary institution must meet the minimum requirement of satisfying all the U.S. Transplant Center Participation Criteria.

    b. The secondary institution(s) must demonstrate evidence of functional unity with the primary institution for the past year (at the minimum) and must have performed allogeneic transplants in the past year.

6. Center must have adequate staff, resources, space, equipment, and supplies to perform and manage activities.

7. Centers participating in human subject research must hold a Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP).

PERSONNEL AND TRANSPLANT TEAM

8. Center must designate an NMDP medical director who is a licensed physician, qualified by training and experience to perform and/or supervise defined center activities and meet the following requirements:

    a. Must be board certified (or non-United States [U.S.] specialist certification equivalent) in one or more of the following specialties:

        - Hematology
        - Immunology
        - Medical Oncology
        - Pediatric Hematology/Oncology

        NOTE: 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.

    b. Must be responsible for search management activities and protecting the safety of the recipient.

    c. Must have at least two years of experience (within the past five years) as an attending physician responsible for clinical management of allogeneic transplant recipients in inpatient and outpatient settings.

    d. Must participate in annual educational activities related to the field of hematopoietic cell transplantation (at least one continuing medical education [CME] credit hour).

9. Center must have at least two attending physicians (including the NMDP medical director) and they must meet the following requirements:

    a. Are licensed physicians

    b. Are qualified by training and experience in allogeneic hematopoietic cell transplantation

        NOTE: 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 continuous 12-month coverage for both the inpatient unit and outpatient clinic

    d. Must be board certified (or non-U.S. specialist equivalent) or eligible in one or more of the following specialties:

        - Hematology
        - Immunology
        - Medical Oncology
        - Pediatric Hematology/Oncology

e. Must participate in annual 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 ten different patients per year and must demonstrate that allogeneic recipients achieved survival rates acceptable to NMDP.

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 coordinators 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 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. Additional requirements include:

    a. A laboratory certified by CMS for clinical laboratory tests required by NMDP.

    b. A laboratory accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), and/or the College of American Pathologists (CAP) for human leukocyte antigen (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. A laboratory that can detect cytomegalovirus (CMV) infection by quantitative polymerase chain reaction (qPCR), viral culture, antibody tests, or equivalent and provide results within 72 hours.

    d. A laboratory that can count the number of nucleated cells and quantify CD34+ cells in hematopoietic progenitor cells (HPC)A products.

    e. A laboratory that can confirm ABO grouping and Rh typing of HPC(M) or HPC(A) products, or blood obtained from the donor at the time of collection.

f. A laboratory that can perform fungal and bacterial cultures on products received.

g. Transfusion service(s) that provides 24-hour blood component support for transplant patients, including irradiated blood components and components suitable for CMV-negative recipients.

18. Center must have access to persons 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:

- Cardiology
- Gastroenterology
- Infectious Disease
- Intensive Care
- Nephrology
- Pathology
- Pulmonary Medicine
- Psychiatry
- Surgery
- Transfusion Medicine
- Radiation Therapy (if applicable)

20. Center must have sufficient staff from at least the following services:

- Dentistry
- Dietary
- Pharmacy
- Physical Therapy
- Respiratory Therapy
- Social Services

21. Center must have prompt technical and operational support for information systems management.

POLICIES AND PROCEDURES

22. Center must maintain the following minimum requirements for written policies and/or procedures:

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

g. Education of the patient pre- and post-transplant

23. Each recipient of hematopoietic cells from 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 the following minimum requirements for written clinical practice guidelines:

- Criteria for patient eligibility
- Patient evaluations
- Preparative regimens for transplantation
- Prevention and treatment of graft-versus-host disease
- CMV prophylaxis, surveillance and treatment
- Post-transplant care

25. Center must have a quality assurance program designed to meet the NMDP minimum requirements to promptly identify, process, report, and prevent (if applicable) the following:

- Adverse events
- Deviations
- Complaints
- Nonconforming products, materials, or services
- Corrective actions and preventive actions

26. Center must maintain relevant records, in accordance with PL-00109, *NMDP Participating Network Centers Record Retention Policy*, to ensure the identification and traceability/trackability of each donor and cellular therapy product and all related samples including:

a. From the initial source, through each processing and testing step to the final disposition

b. From final disposition, through each processing and testing step back to the initial source

27. Center must retain records in accordance with PL-00109, *NMDP Participating Network Centers Record Retention Policy*.

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 of records that meets or exceeds NMDP requirements for the protection of privacy of potential donors (registry members), donors, patients, and recipients.

PATIENT ADVOCACY

30. Center must have policies to ensure timely communication with patients, families, and physicians, including the progress of the search and other treatment options.

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.

    a. The center may designate NMDP Patient and Health Professional Services as the patient advocate.

33. Center 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 meet established continuous process improvement (CPI) criteria.

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

37. Center must have readily available Internet access capable of exchanging search results, daily reports, vital information, transplant dates, and data with NMDP.

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

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

40. Center must maintain adequate professional and general liability insurance coverage, as required in the participation agreement.

41. Center must promptly report to NMDP any significant changes in personnel including but not limited to the medical director, coordinator, facilities, accreditations, or support services.

APPLICANT CENTERS

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

    a. Applicant center must have performed primary allogeneic transplants for at least 10 different patients per year during the previous 12 months to qualify as a transplant center.

    b. Applicant center must submit a "Hematopoietic Stem Cell Transplant History" form documenting all allogeneic transplants for the previous 12 months, to include the day +100 status for each patient. Experience must demonstrate that the applicant center achieved appropriate allogeneic recipient survival rates.

    c. 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.

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