

**NATIONAL MARROW DONOR PROGRAM®**  
**TRANSPLANT CENTER PARTICIPATION CRITERIA**

Transplant Center criteria have been adopted by the NMDP to ensure that hematopoietic stem cells from unrelated donors will be transplanted at institutions experienced in allogeneic stem cell transplantation. All Transplant Centers participating in the NMDP shall meet these criteria on an ongoing basis and demonstrate compliance with the Standards of the NMDP.

**FACILITY CHARACTERISTICS**

1. The center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association's Healthcare Facilities Accreditation Program (HFAP), or non-US equivalent.
2. The center shall have a designated inpatient unit that minimizes airborne contamination.
3. Center shall have a designated site for management of search activities.
4. The center shall have a designated area for outpatient evaluation and treatment available 24 hours per day and seven days per week, that reduces the risk of transmission of infectious agents.
5. A center with geographically non-contiguous patient care units shall demonstrate functional unity through shared mechanisms such as:
  - medical director
  - coordinator
  - standard operating policies and procedures
  - data management
  - cell processing laboratory
  - training of support personnel
6. If the patient care units are located in more than one institution, at least one institution shall satisfy all transplant center participation criteria individually. Patient care units at any other institution shall have performed allogeneic transplants for at least four different patients per year. Separate units operating independently (not components of a single transplant program), shall satisfy all transplant center participation criteria individually.
7. Applicant centers shall submit a completed "Hematopoietic Stem Cell Transplant History" Form documenting all allogeneic transplants for up to the previous twenty-four months, to include the day +100 status for each patient. At the time of annual accreditation, center shall document transplants performed in the past 12 months. Experience shall demonstrate that allogeneic recipients achieved appropriate survival.

## **PERSONNEL AND TRANSPLANT TEAM**

8. Center shall have adequate resources to support its search management activities.
9. Applicant facility and medical team, including medical director and at least one other attending physician experienced in allogeneic transplantation shall have been performing transplants at that site for at least one year.
10. Center shall have an experienced team that has performed allogeneic transplants for at least 10 different patients per year. Applicant centers shall 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.
11. Centers performing pediatric transplants shall have a transplant team trained in the management of pediatric patients.
12. Center shall have at least two attending physicians who are licensed and qualified by training and experience in allogeneic hematopoietic progenitor cell transplantation. Adequate clinical training in allogeneic hematopoietic progenitor cell transplant shall be defined as a minimum of one year experience in the management of transplant recipients in both the inpatient and outpatient settings.
13. The center shall have a medical director who is a licensed physician and who shall be responsible for search management activities and protecting the safety of the recipient.
14. The center medical director shall be board certified (or non-US 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 medical directors if they have documented experience in the field of hematopoietic progenitor cell transplantation extending over ten years. The center's attending physicians should be board certified or eligible (or non-U.S. equivalent) in the specialties listed above.
15. The center medical director shall have had at least two years experience as an attending physician responsible for clinical management of allogeneic hematopoietic cell transplant recipients in the inpatient and outpatient settings.
16. Center medical director and attending physicians shall participate regularly in educational activities related to the field of hematopoietic progenitor cell transplantation (at least one CME credit hour or non-U.S. equivalent per year).
17. The center shall provide daily and emergency coverage by designated transplant coordinator(s), fluent in English, sufficient in number to meet the needs of the center's activities.
18. The center shall have nurses qualified by training and experience in the care of transplant recipients, sufficient in number to meet patient needs.
19. The center shall have sufficient data management personnel to comply with the NMDP data submission requirements.

## **SUPPORT SERVICES**

20. The center shall use an HLA laboratory(ies) accredited by the American Society of Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI) for techniques required by NMDP. The laboratory designated by the transplant center is responsible for the final HLA typing of the patient and donor.
21. Center shall utilize a person qualified by training and experience in human histocompatibility testing to assist in the selection of unrelated hematopoietic progenitor cell donors.
22. The center shall utilize laboratory(ies) certified by CLIA (or non-US equivalent) for all clinical laboratory tests required by NMDP.
23. Center shall use a transfusion service providing 24-hour blood component support for transplant patients, including irradiated blood components and components suitable for CMV-negative recipients.
24. Center shall use an experienced hematopoietic progenitor cell processing laboratory.
25. Center shall 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.
26. Center shall have sufficient staff from at least the following services: pharmacy, dentistry, dietary, social services and physical therapy.

## **POLICIES AND PROCEDURES**

27. Center shall maintain written policies and procedures to address at least the following:
  - Donor Selection
  - Financial Approval
  - Infection prevention and control
  - Processing ABO incompatible progenitor cell products to reduce red cell content
  - Hematopoietic cell infusion
  - Blood component transfusion to include transfusion of blood components when the donor and recipient are ABO mismatched
  - Pre and post-transplant education for the patient
28. Each recipient of hematopoietic progenitor cells from an NMDP donor shall 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.
29. Written clinical practice guidelines shall include at least the following:
  - Criteria for recipient selection
  - Procedures for recipient evaluations
  - Preparative regimen for transplantation

- Procedures for the prevention and treatment of graft-versus-host disease
  - CMV prophylaxis, surveillance and treatment
  - Procedures for post-transplant care
30. Use of hematopoietic progenitor cells from an NMDP donor shall require provision to obtain written consent from the recipient for the submission of data and blood samples to the NMDP.
31. US centers shall provide evidence of compliance with the Office of Human Research Protection (OHRP) requirements for a Federalwide Assurance, or have a multiple project assurance or single project assurance that has not expired. Non-US centers shall provide evidence of compliance with Independent Ethics Committees (IEC) within their country.

**PATIENT ADVOCACY**

32. Center shall communicate the appropriate information about the progress of a search to patients, families and physicians.
33. If a compatible donor is not found, according to the criteria of the transplant center, the patient shall be informed of other options including:
- Referral to approved transplant centers whose criteria for unrelated transplants are different
  - Repeated NMDP search results as more donors are added
  - Search results of other registries
34. The center shall have a patient advocate who is familiar with the center's transplant program and issues of unrelated donor hematopoietic cell transplantation, but is not a member of the transplant team.

**ADMINISTRATIVE**

35. The center shall acknowledge financial responsibility for services requested by the center and rendered by the NMDP.
36. The center shall have readily available access to the Internet through which search results, daily reports, vital information, transplant dates and data are reported. A readily available computer adequate to run the TRANS Link™ software application, modem, and printer are required. No search requests or interactions will be facilitated until access to the Internet is established.
37. The center shall maintain adequate professional and general liability insurance coverage. Minimum required levels:
- |                              |                              |
|------------------------------|------------------------------|
| General Liability            | Professional Liability       |
| \$1 million per occurrence   | \$1 million per occurrence   |
| \$2 million annual aggregate | \$3 million annual aggregate |
38. The center shall comply with NMDP Standards, policies and procedures that include but are not limited to Continuous Process Improvement (CPI) criteria, and shall document on an annual basis that transplant center participation criteria are met. Any significant changes in personnel, facility or support services shall be reported promptly to the NMDP.