

## Criteria for Affiliated Transplant Centers

### 1.0 Transplant Centers Meeting Criteria

- The transplant center must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), the American Osteopathic Association's Healthcare Facilities Accreditation Program (HFAP), or non-U.S. equivalent.
- The transplant center must be in compliance with appropriate national and international regulations.
- The centers shall have a designated inpatient unit that minimizes airborne contamination.
- The center shall have a designated site for management of search activities.
- 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.
- The 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 and Support Personnel
- If the patient care units are located in more than one institution, at least one institution shall satisfy all transplant center participation criteria individually.
- The transplant center shall have performed at least ten allogeneic transplants in each of the two years preceding a request for cellular collection and shall be expected to maintain this level of clinical activity.
- The transplant center should agree to maintain membership in and to report clinical data covering allogeneic transplantation on a regular basis to an appropriate national or international agency (such as the European Group for Bone Marrow Transplantation (EBMT) or the Center for International Blood and Marrow Transplant Research (CIBMTR) or other nationally organized body).

## Criteria for Affiliated Transplant Centers

- Regular publication of clinical data in peer-reviewed journals may be accepted as an alternative to regular reports to agencies.
- Transplant centers should agree, in principle, to a site visit.
- The transplant center shall have adequate professional and general liability insurance.
- Continued adherence to The Caitlin Raymond International Registry (CRIR) standards shall be confirmed, as requested, by CRIR. These documents must be forwarded to the registry providing the donor, if requested.

### 2.0 Personnel and Transplant Team

- The Center shall have adequate resources to support its search management activities.
- The Medical Team shall have experience in allogeneic transplantation and have been performing transplants at the site for at least two years.
- Centers performing pediatric transplants shall have a transplant team trained in the management of pediatric patients.
- The Center shall have a medical director who shall be board certified (or non U.S. 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.
- 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.
- The Center medical director and attending physicians shall participate regularly in educational activities related to the field of hematopoietic progenitor cell transplantation.
- The Center shall provide daily and emergency coverage by designating transplant coordinator(s) sufficient in number to meet the needs of the center's activities.

## Criteria for Affiliated Transplant Centers

- The Center shall have nurses qualified by training and experience in the care of transplant recipients, sufficient in number to meet patient needs.

### 3.0 Support Services

- The Center shall use an HLA laboratory accredited by the American Society of Histocompatibility and Immunogenetics (ASHI) or the European Federation for Immunogenetics (EFI). The laboratory designated by the Transplant Center is responsible for the final HLA typing of the patient and donor.
- The 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.
- The Center shall utilize a laboratory certified by CLIA (or non-U.S. equivalent) for all clinical laboratory tests.
- The 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.
- The Center shall use an experienced hematopoietic progenitor cell processing laboratory.
- The Center shall have experienced physicians who provide consultative services in at least the following disciplines: surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious disease, cardiology, pathology, psychiatry, and, if applicable, radiation therapy.
- The Center shall have sufficient staff from at least the following services: pharmacy, dentistry, dietary, social services and physical therapy.

### 4.0 Policies and Procedures

- The 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

## Criteria for Affiliated Transplant Centers

- 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
- 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-verses-host disease
  - CMV prophylaxis, surveillance and treatment
  - Procedures for post-transplant care

### 5.0 Patient Advocacy

- The Center shall communicate the appropriate information about the progress of a search to patients, families and physicians, as appropriate and authorized.
- 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
  - Repeat search results as more donors are added to the registry
  - Search results of other registries
- 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.

### 6.0 Administrative

- The Center shall have readily available access to the internet and fax through which search results, daily reports, vital information, transplant dates and data are reported.
- The Center shall maintain adequate professional and general liability insurance coverage.
- The Center shall report any changes in key staff.