ABRIDGED STANDARDS FOR TCs ONLY

GIFT OF LIFE MARROW REGISTRY

STANDARDS

The purpose of this document is to outline the general operational guidelines of the Gift of Life Marrow Registry. This document does not detail specific procedures. All standards stated or implied are expected to comply with all applicable federal and local regulatory requirements and generally accepted industry standards. The Registry is expected to comply with those standards promulgated by the World Marrow Donor Association that are consistent with federal and local law.

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3. TRANSPLANT CENTER CRITERIA

3.1. Personnel

3.1.1. Transplant Center Medical Director

A. The Transplant Center Medical Director shall be appropriately licensed (or non-U.S. equivalent) in one or more of the following specialties: Hematology, Immunology, Medical Oncology or Pediatric Hematology/Oncology.
B. The Transplant Center Medical Director shall have a minimum of two years of experience as an attending physician responsible for the direct clinical management of allogeneic transplant recipients in the inpatient and outpatient settings.
C. The Clinical Program Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

3.1.2. Transplant Center Attending Physician

A. Attending physicians shall be appropriately licensed to practice medicine and should be a specialist certified or trained in one (1) of the following specialties: Hematology, Medical Oncology, Immunology or Pediatric Hematology/Oncology.
B. Clinical Programs performing adult transplantation shall have at least one (1) attending physician who has achieved specialist certification in Hematology, Medical Oncology or Immunology.
C. Attending physicians shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

3.1.3. Search Coordinator

The search coordinator shall be dedicated to the center's donor search management activities, and shall have a strong understanding of the search process, tissue typing methodologies, antigen specificities and HLA nomenclature.

3.1.4. Data Management Personnel

The center shall have sufficient data management personnel to comply with the Registry's data submission requirements in a timely manner.

3.1.5. Transplant Center Support Staff

Sufficient personnel possessing relevant experience and qualifications shall be available to support TC operations. Key staff should be readily accessible via telephone, fax, pager, and e-mail.

3.2. Laboratories

3.2.1. HLA Tissue Typing Laboratory

The Transplant Center shall use an HLA typing laboratory accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), the European Federation for Immunogenetics (EFI), and/or the College of American Pathologists (CAP) or other equivalent non-US accreditation. The Transplant Center's laboratory is responsible for the final HLA typing of the patient and donor.

3.2.2. Blood Services

The Transplant 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.

3.2.3. Stem Cell Laboratory

The Transplant Center shall use an experienced hematopoietic stem cell processing laboratory.

3.3. Facility Requirements

3.3.1. The TC shall have an experienced team that has performed allogeneic transplants.

3.3.2. The TC shall have adequate physical resources to run an HPC transplant program. Physical resources shall include, but are not limited to, a designated inpatient unit, a designated site for management of search activities, and a designated area for outpatient evaluation and treatment.

3.3.3. A TC performing pediatric transplants shall have a transplant team trained in the management of pediatric patients.

3.3.4. Key TC staff shall be readily accessible via telephone, e-mail and fax.

3.3.5. The TC shall obtain IRB approval of any transplant protocols for which the TC's IRB considers necessary.

3.3.6. The TC shall be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS) or non-U.S. equivalent.

3.4. Responsibilities

3.4.1. The TC shall maintain written policies, procedures and clinical guidelines for management of allogeneic transplantation, and related quality assurance and improvement processes.

3.4.2. The TC shall ensure that its patients for whom Registry donors are requested to donate HPCs receive appropriate informed consent for their procedures and the use of the particular donors whose HPCs are intended for transplantation, including any unusual donor test results or characteristics that might increase the risk of transplantation-related harm to the recipient.

3.4.3. The TC is responsible for reporting adverse events to regulatory agencies as required by law and to applicable accrediting agencies as required by the terms of accreditation, and to GOL, in a timely manner.