ABRIDGED STANDARDS FOR CCs

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.

Gift of Life Marrow Registry
5901 Broken Sound Parkway, Suite 600
Boca Raton, Florida 33487
Tel: 561.982.2900
Fax: 561.982.2901

TABLE OF CONTENTS

2. COLLECTION CENTER CRITERIA

2.1. Standards and Regulations

2.1.1. The CC must meet at a minimum the criteria listed in the WMDA Standards as well as national regulations and laws.

2.1.2. The Registry and CC shall ensure a system is in place to ensure that WMDA Standards are followed.

2.1.3. The CC must be registered by relevant governmental authorities, if applicable, and adhere to applicable national and international regulations.

2.1.4. The CC should be accredited by an organization representing standards for high quality medical and laboratory practice in cellular therapies such as AABB or FACT.

2.1.5. The CC should be approved by the NMDP.

2.1.6. The CC must report any changes to their accreditation and licensing status to Gift of Life in a timely fashion.

2.2. Quality Systems

2.2.1. National and Gift of Life-specific requirements concerning quality and safety procedures must be met.

2.2.2. The CC must take all necessary measures to ensure donor safety, high quality of HPC products and appropriate donor management at all times during the work-up and follow-up procedures.

2.2.3. The CC must have a quality management system in place.

2.3. Personnel

2.3.1. Collection Center Medical Director

A. The CCMD shall be a licensed physician with training in human histocompatibility, immunology, and the procurement and transplantation of HPCs.

B. The CCMD is responsible for safeguarding the health of the donor and ensuring the safety of the HPC product.

C. The CCMD shall perform and/or review a complete medical evaluation of the donor to determine if the donor is an acceptable candidate for collection including evaluation of the donor for risks of donation and evidence of disease transmissible by transplantation.

2.3.2. Collection Center Support Staff

A. Any persons assisting in the bone marrow harvest shall have documented adequate training in marrow collection for transplantation.

B. Sufficient personnel possessing relevant experience and qualifications shall be available to support CC operations, including emergency coverage.

C. Staff training must include reference to the altruistic and voluntary nature of the procedure that the donor is undergoing and that as a result appropriate consideration should be given to the donor.

2.4. Responsibilities

2.4.1. The CCMD or designee is generally responsible for establishing the donor's suitability to donate, and in some cases the donor's eligibility to donate, in accordance with relevant regulatory requirements.

2.4.2. The CC's medical staff is responsible for the donor's safety and care throughout the pre-collection, collection and post-collection process.

2.4.3. The attending physician assigned by the CC to the donor shall not have a vested interest in the patient aspect of the coordination process.

2.4.4. The CC is responsible for reporting adverse events and positive infectious disease test results to Gift of Life.

2.4.5. The CC is responsible for obtaining informed consent from the donor before undergoing the HPC or MNC collection, or any other procedure.

2.5. Marrow Collection Criteria

2.5.1. Collection Center Medical Director

A. The CCMD shall have at least two years' experience in bone marrow collection or have performed at least ten bone marrow collection procedures within his/her career.

B. The CCMD shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually to maintain and enhance their knowledge.

2.5.2. Anesthesiologist

The anesthesiologist shall be a board-certified licensed physician or certified nurse anesthetist.

2.5.3. Collection Center Staff

The Collection Center staff shall be experienced healthcare professionals, trained and experienced in the collection of HPC, Marrow.

2.5.4. Facility Requirements

A. The CC shall have an experienced team adequate for the number of procedures performed.

B. The CC shall be accredited by TJC.

C. The CC shall be accredited by an organization granted deemed status by Centers for Medicare & Medicaid Services (CMS).

D. The CC shall have a surgical operating room and a surgical or medical intensive care unit.

E. The CC shall verify that autologous units of blood, if collected, are available and stored appropriately.

F. The CC shall have irradiated and luekoreduced blood components available in the event that the use of allogeneic blood is required.

G. The CC shall discharge the donor on the same day as the collection unless a medical issue precludes the donor's release, or the CC's policy is to monitor the donor overnight.

2.6. Apheresis Center Criteria

2.6.1. Apheresis Center Medical Director

A. The ACMD shall be a licensed physician with a minimum of two years' postgraduate certification, with training and practical relevant experience in cellular therapy product collection and transplantation.
B. The ACMD shall perform or supervise a minimum of five (5) cellular therapy product apheresis collection procedures in twelve (12) months.
C. The ACMD shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually to maintain and enhance their knowledge.

2.6.2. Apheresis Center Physician

A. A licensed physician, with experience in the administration and management of complications, is responsible for the prescribing of mobilizing agents and prescribing home healthcare administration.
B. Access to an experienced medical professional qualified by training and experience for the placement of a central venous line, when required.

2.6.3. Facility Requirements

A. The AC shall have an experienced team that has performed at least five apheresis collections in the past year.
B. The AC shall be registered with the FDA for the related donor activities it performs as part of its contractual agreement with the Registry.
C. The AC should be accredited by TJC, when appropriate.
D. The AC shall have an active IRB-approved protocol for administration of growth factor to healthy unrelated HPC-A donors.
E. The AC shall maintain written standard operating procedures for peripheral venous access assessment, placement and determination of adequacy of line placement.
F. The AC shall have primary and backup apheresis equipment, supplies and pharmaceuticals.

2.7. Equipment and Supplies

2.7.1. The CC must have and maintain adequate resources, equipment, supplies, and pharmaceuticals to support its collection and associated management activities.
2.7.2. The CC must operate an appropriate IT system (hardware, software, and network) to cover donor management, communications and the HPC collection.

2.8. Facility Requirements

2.8.1. The CC must have a designated site for the management of collection activities, and a secure environment for confidential record storage.
2.8.2. The CC must have controlled storage areas to prevent mix-ups, contamination, and cross-contamination of products.
2.8.3. Key CC staff shall be readily accessible via telephone, e-mail and fax.
2.8.4. The CC must have an emergency phone that is available 24 hours per day, 7 days per week, all year long from the time of the physical examination, through the donation process, until the donor has fully recovered.
2.8.5. The CC shall have a written agreement which defines roles and responsibilities with GOL.

2.8.6. The CC shall provide a detailed fee schedule of all pre-collection and collection services, and provide notice of changes in costs at least three months in advance of rendering services.
2.8.7. The CC shall maintain written standard operating procedures for pre-collection, collection and post-collection activities.
2.8.8. The CC shall provide post-donation care instructions with contact names and phone numbers.

2.9. Data and Records

2.9.1. The CC must have systems in place to prevent unauthorized access to donor and recipient data, both electronic and in paper format.
2.9.2. When transmitting donor or patient data, the CC must have systems that ensure data privacy and security.
2.9.3. The CC must ensure proper documentation of all process steps and communication with the donor, either electronically or in paper format, to ensure confidentiality and to allow for traceability of the donor and product throughout all steps of the donation and post-donation recovery process.
2.9.4. The CC must maintain records for an appropriate period of time, in accordance with national laws and regulations.

2.10. Communication with the Transplant Center

The CC may not communicate with the TC unless there are exceptional circumstances and prior approval has been obtained from the Gift of Life.