



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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GIFT OF LIFE MARROW REGISTRY STANDARDS

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ACRONYMS

AC	Apheresis Center
ACMD	Apheresis Center Medical Director
ASHI	American Society of Histocompatibility and Immunogenetics
BMDW	Bone Marrow Donors Worldwide
CAP	College of American Pathologists
CC	Collection Center
CCAP	Collection Center Attending Physician
CCMD	Collection Center Medical Director
CLIA	Clinical Laboratory Improvement Amendments
CR	Cooperative Registry
CT	Confirmatory Typing
DDS	Director of Donor Services
DSMD	Donor Services Medical Director
EFI	European Federation for Immunogenetics
ET	Extended Typing
FDA	Food and Drug Administration
GOL	Gift of Life Marrow Registry
HLA	Human Leukocyte Antigen
HPC	Hematopoietic Progenitor Cells
HPC-A	Hematopoietic Progenitor Cells, Apheresis The terms “HPC-A” and “Peripheral Blood Stem Cells” may be used interchangeably
HPC-M	Hematopoietic Progenitor Cells, Marrow The terms “HPC-M” and “Bone Marrow” may be used interchangeably
IDM	Infectious Disease Markers
IS	Information Systems
IT	Information Technology
MNC-A	Mononuclear Cells, Apheresis The terms “MNC-A” and “T Cells” may be used interchangeably
NMDP	National Marrow Donor Program
QA	Quality Assurance
RMD	Registry Medical Director
SCU	Search Coordination Unit
TC	Transplant Center
TJC	The Joint Commission
WMDA	World Marrow Donor Association

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DEFINITIONS

Apheresis Center is defined as a type of CC that performs PBSC and/or T Cell collections. The term “Apheresis Center” may be used in lieu of “Collection Center” when referring to PBSC or T Cell collections only.

Collection Center is defined as a hospital performing a bone marrow harvest, a PBSC collection, or a T Cell collection. CCs are responsible for performing the donor’s Physical Exam, establishing donor eligibility and suitability, and procuring the product. The CC is considered to be the caregiver responsible for assuring the donor’s safety and well-being during and immediately after the collection process.

Cooperative Registry is defined as a domestic or international registry searching for potential donors on behalf of transplant centers. A CR is responsible for ensuring that any TC working with GOL through that CR adheres to GOL Standards, WMDA Standards and regulatory requirements in their respective countries.

Donor Selection is defined as the process of evaluating medical history, screening and testing results and Physical Exam records of a prospective donor for the purpose of determining preliminary donor eligibility and suitability for adult stem cell donors.

Donor Services is defined as the Registry department responsible for managing all test requests made after the preliminary search request. This includes but is not limited to CT, ET, Workup and Follow-up.

Eligibility is defined as the donor having no history, signs or risks of relevant communicable disease agents and diseases based on screening and testing as described in 21 CFR Part 1271, Subpart C. The establishment of donor eligibility is the responsibility of the CC attending physician.

Formal Search, also known as “**Activation**,” is defined as the point at which a TC or CR’s SCU requests additional testing of any donors after the preliminary search is performed. Searches may only be activated by TCs.

Hematopoietic Progenitor Cells (HPC) are defined as the human precursor or progenitor cells derived from bone marrow and peripheral blood.

MatchQuest[®] is defined as a proprietary computer application developed by GOL to manage all aspects of Registry operations. MatchQuest[®] facilitates the addition of donor information into the Registry’s database, automates many case management tasks associated with the donation process, automates much of the search process, and interfaces with various other computer systems used by external entities that exchange information with the Registry.

Preliminary Eligibility is defined as the donor having been evaluated at a certain stage of the donation process and being eligible to proceed to the next step. For example, after completing the Consent Form at Recruitment, if the donor’s screening questionnaire does not give a reason for deferral, they have preliminary eligibility and are available to appear in the Registry. At Confirmatory Typing, if the IDM results are negative, and no risk factors are indicated by the screening questionnaire then the donor has preliminary eligibility and may proceed to Work-up, if requested.

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Preliminary Search is defined as an initial screening of the donor file that generates a list of potential donors matching a given patient. Preliminary searches may be requested by a patient's primary care physician, a TC, or the SCU of a CR.

Registry is defined as the organizational administrative headquarters responsible for overseeing the activities of the Donor Services department, SCU and patient advocacy program, and interfacing with the CC, TC, and laboratories.

Suitability A donor is suitable when the CC physician has determined that the donor does not have a known condition that will present a risk to the donor to donate. The establishment of donor suitability is the responsibility of the CC attending physician.

Transplant Center is defined as the medical center that is searching for a donor with matching HLA for their patient and that will perform the actual transplantation procedure.

THE ROLE OF THE GIFT OF LIFE MARROW REGISTRY

Gift of Life maintains a computerized registry of potential volunteer bone marrow and blood stem cell donors. Transplant centers may search the registry in order to identify potential donors whom they consider appropriately matched with the patients under their care.

Gift of Life enrolls donors in its registry through recruitment drives, conducts preliminary eligibility screening of donors, and serves as a liaison between donors, collection centers and transplant centers. While Gift of Life coordinates these activities, it does not select appropriate "matches" for patients needing transplants; establish final eligibility and suitability of HPC, Marrow, HPC, Apheresis or MNC, Apheresis donors; prescribe or administer medications for/to donors; or harvest HPC, Marrow, HPC, Apheresis or MNC, Apheresis. These activities are undertaken by collection centers and transplant centers.

GIFT OF LIFE MARROW REGISTRY STANDARDS

THE STANDARDS

1. REGISTRY CRITERIA

1.1. Administration

1.1.1. Personnel

A. Registry Medical Director

1. The RMD shall be a licensed physician having expertise in human histocompatibility, HPC transplantation and immunology.
2. The RMD may also serve as the DSMD.

B. Chief Executive Officer

1. The Chief Executive Officer shall have appropriate administrative, managerial and budgetary experience and background to oversee daily operations and plan for future development and growth.
2. The Chief Executive Officer shall understand the current national and international network of CRs and affiliates, applicable regulatory requirements, and generally accepted industry standards.

C. Board of Directors

The Board of Directors shall collectively possess appropriate administrative, managerial, and financial experience and background to effectively oversee Registry operations by setting policies consistent with the Registry's stated mission, selecting executives who can carry out the mission, and monitoring the Registry's performance.

D. Medical Advisory Committee

The Registry shall have a medical review panel to assist with making unbiased decisions regarding nonstandard, high risk or experimental HPC donation or other related procedures.

The committee shall include one or more expert consultants in the areas pertinent to the operation of the Registry to assist in establishing policies and procedures. The Registry should have direct access to the consultant(s). The consultant(s) shall collectively have backgrounds in, but not limited to, the areas of HPC transplantation, microbiology, clinical pathology, infectious diseases, histocompatibility and immunogenetics.

E. Registry Support Staff

Sufficient personnel shall be available to support Registry operations, including those with experience in human resources, marketing and communications, and institutional development and advancement.

1.1.2. Facility Requirements

- A. Each division of the Registry shall be provided with sufficient space so that work can be carried out in an environment designed to minimize errors and maintain confidentiality. Divisions that are involved in donor relations and patient relations shall be provided with space that physically separates one from the other.
- B. Each division shall provide staff with the ability to lock confidential files, and engage in private meetings and telephone conversations.

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- C. Each division shall have sufficient communication links and technology resources, including, but not limited to, telephone, fax, computers and Internet access.

1.2. Donor Services Department

1.2.1. Personnel

A. Donor Services Medical Director

1. The DSMD shall be a licensed physician with expertise in human histocompatibility, immunology, and the procurement and transplantation of HPCs.
2. The DSMD may designate a manager to perform certain tasks on his or her behalf, whom s/he considers to be a responsible person based on training and qualifications.
3. The DSMD may also serve as the RMD.

B. Director of Donor Services

1. The DDS shall have a strong understanding of BM/PBSC/T Cell donor solicitation and selection, workup case management, and product procurement.
2. The DDS shall have sufficient administrative experience in a healthcare environment to oversee day-to-day program operations.
3. The DDS shall be familiar with applicable regulatory requirements and generally accepted industry standards.
4. The DDS shall not have a vested interest in the patient aspect of the coordination process and shall be able to offer unbiased counseling to prospective donors.
5. The DDS shall be available via cell phone in the event of an emergency during non-business hours.
6. The DDS is responsible for ensuring that written standard operating procedures are maintained for all aspects of the department, including but not limited to CT, ET, donor workup case management, product labeling and transport, donor follow-up and subsequent donation requests.
7. The DDS shall review the manuals of procedures and ensure that the manuals are updated as necessary to reflect changes in management, policy, reporting and coordination requirements.
8. The DDS shall ensure that there is adequate staff to accommodate unusually high workload and staff absences.

C. Donor Services Staff

1. Sufficient personnel possessing relevant experience and qualifications who are trained and knowledgeable about their duties shall be available to support operations.
2. Donor Services staff shall be appropriately cross-trained and staff schedules shall be coordinated to ensure that sufficient personnel are available to perform all necessary tasks.

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1.2.2. Support Resources

- A. Donor Services shall have written agreements with CCs for establishing donor eligibility and suitability and performing bone marrow harvests and apheresis collections in geographic locales that support its donor base.
- B. Donor Services shall have written agreements with laboratories that perform HLA tissue typing, infectious disease testing and other required clinical testing.
- C. Contracted facilities shall comply with participation criteria specified in these and the WMDA Standards.
- D. The donor shall have access to the support of a donor advocate during ET, CT and Workup. The advocate shall meet the following criteria: No vested interest in the decision about BM/PBSC/T Cell donation and transplantation; a good understanding of the BM/PBSC/T Cell donation process and risks of donation; demonstrated skill in effective interpersonal communication within an organizational setting; and not an employee of the Registry.

1.3. Search Coordination

1.3.1. Personnel

A. Search Coordinator

- 1. The search coordinator shall have an understanding of the search process, tissue typing methodologies, antigen specificities and HLA nomenclature.
- 2. The search coordinator shall have access to expert consultants for search advice.

B. Patient Advocate

- 1. The patient advocate shall be available when necessary to provide patients with guidance concerning related and unrelated donor search strategies, including access to all sources of HPCs worldwide.
- 2. The patient advocate shall have a strong understanding of the diseases treated by HPC transplantation, the related and unrelated donor search process, the transplant process, and insurance-related issues.

C. Search Coordination Support Staff

Sufficient personnel possessing relevant experience and qualifications shall be available to support search coordination activities.

1.3.2. Registry Access

- A. The Registry shall be available to all patients worldwide.
- B. Diseases considered eligible for transplantation are those promulgated by the NMDP.
- C. Donor HLA phenotypes and other non-identifying characteristics shall be available for search through BMDW and updated according to BMDW's pre-determined schedule.
- D. Physicians not affiliated with participating TCs may initiate preliminary searches.
- E. Formalization of a search shall be requested by a participating TC or a CR representing a TC.

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- F. TCs are responsible for donor selection. However, the minimal match criteria require at least a 6/8 match at an antigen level (serologic split) for HLA A, B, C and DR.
- G. Minimal match criteria must be met prior to donation for a specific patient. Exceptions may be made by the RMD in cases when no other more appropriate donor is available.

1.3.3. Reporting

- A. Critical communications shall be in writing, either via e-mail or fax.
- B. Results of preliminary searches shall be reported within one business day. If a result cannot be reported in that time, the Registry shall promptly notify the requester of the delay.
- C. Reports shall be designed to protect donor anonymity.

1.3.4. Procedures

The search coordinator shall maintain a written manual of procedures on all aspects of the search process, including, but not limited to: credentialing applicant TCs and CRs, provisioning database search access and search requests.

1.4. Quality Assurance

1.4.1. Personnel

A. Director, Quality Assurance & Regulatory Compliance

- 1. The Director shall have appropriate experience and background in quality assurance to keep the Registry in compliance with relevant regulatory and accrediting agencies.
- 2. The Director shall understand all current regulations and generally accepted industry standards that apply to the Registry and its affiliates.
- 3. The Director shall be a qualified auditor.
- 4. The Director shall be responsible for maintaining the Registry's continuous process improvement program.

B. Quality Assurance Support Staff

Sufficient personnel possessing relevant experience and qualifications shall be available to support regulatory and compliance requirements.

1.4.2. Responsibilities

- A. QA shall develop, maintain and manage a quality plan that assures compliance with applicable requirements and standards instituted by regulatory and accrediting agencies with or by whom the Registry is licensed, registered, accredited, or otherwise regulated. This plan shall include but is not limited to the following systems and programs:
 - 1. QA shall maintain a document management system to ensure appropriate document control.
 - 2. QA shall maintain a change management system to manage and track change history.
 - 3. QA shall maintain a deviation and complaint management system including adverse event management and reporting, and a corrective and preventative action program.

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4. QA shall maintain an audit program consisting of the following elements:
 - a. Self-assessments, internal and external auditing.
 - b. Supplier qualification and critical supply qualification.
 - c. Affiliate certifications and accreditations review.
5. QA shall ensure that equipment and processes are validated for their intended use.
6. QA shall work with Registry departments to achieve continual improvement in procedures and operations.
7. QA shall maintain a training program for Donor Services personnel, including annual competency evaluation.
8. QA shall perform or arrange for the performance of preventative maintenance and calibration on critical Registry equipment.
9. All quality management systems, control systems and programs shall be performed in accordance with established standard operating procedures.

1.5. Information Systems & Information Technology

1.5.1. Personnel

Sufficient personnel possessing relevant experience and qualifications shall be available to maintain technology used to perform Registry operations, including but not limited to computer software and hardware.

1.5.2. Responsibilities

- A. IS and IT shall maintain technology required for Registry operations.
- B. IS and IT shall store electronic records and documents using appropriate security and protection.
- C. IS shall validate all proprietary software developed by the Registry that could affect product safety or efficacy, in accordance with relevant regulatory requirements.
- D. IS shall obtain proof of validation for any externally-developed software that could affect product safety or efficacy.
- E. IT shall document the following: installation and upgrades of the system, training and continuing competency of personnel, policies and procedures for system maintenance and operations, ongoing backup procedures, documented and tested procedures for data restoration and offsite storage of electronic data records.
- F. IT shall perform data backup and design appropriate system redundancy to allow for continued operations should conditions render primary systems inoperable or inaccessible.

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1.6. Recruitment Department

1.6.1. Personnel

A. Director of the Recruitment Department

1. The Director of the Recruitment Department shall have the experience to run a department that includes on-site staff, off-site staff and a large number of volunteers.
2. The Director of the Recruitment Department shall be familiar with the recruitment process at donor drives and for online donors.
3. The Director of the Recruitment Department shall be familiar with the WMDA standards that apply to recruiting donors.

B. Recruitment Coordinator

1. The Recruitment Coordinator shall be familiar with the logistics of donor recruitment drives.
2. The Recruitment Coordinator shall be familiar with the WMDA standards that apply to recruiting donors.

C. Recruitment Back Office Coordinator

1. The Recruitment Back Office Coordinator shall be trained in the office practices a they pertain to sending material for a donor drive, processing incoming HLA kits, storing HLA kits and sending HLA kits for testing.
2. The Recruitment Back Office Coordinator shall be trained in the recruitment of online donors.

1.6.2. Responsibilities

A. The Director of the Recruitment Department is responsible for:

1. Providing educational material for donors that meets WMDA standards.
2. Providing training material for off-site staff and volunteers.
3. Ensuring processes are in place to process donor HLA kits in the GOL office, store them and send them to the HLA lab for testing.

B. The Recruitment Coordinator is responsible for ensuring that:

1. Appropriate training is provided to volunteers who assist at a recruitment drive, including confidentiality training.
2. Appropriate donor education is provided during the registration process, including, but not limited to, assuring that educational materials are provided and that informed consent is obtained from each donor recruited.
3. Groups responsible for organizing donor drives on behalf of the Registry adhere to the Registry's recruitment policies.
4. Donors swab correctly and that HLA kits are completed.
5. Donor HLA kits are sent to the GOL office in a timely fashion.

C. The Recruitment Back Office Coordinator is responsible for:

1. Sending HLA kits and material to Recruitment coordinators who carry out drives.
2. Processing incoming HLA kits from drives.
3. Sending HLA kits to online donors.
4. Storing processed HLA kits at the GOL office.
5. Sending HLA kits to the HLA lab for testing.

GIFT OF LIFE MARROW REGISTRY STANDARDS

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, licensed, or accredited by all relevant governmental authorities, and adhere to applicable national and international regulations.
- 2.1.4. The CC should be approved by the NMDP.
- 2.1.5. 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.
- D. The CCMD must participate in educational activities related to HPC collections to maintain and enhance their knowledge.

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 responsible for establishing final donor eligibility and suitability 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.

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- 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 regulatory agencies as required by law and to applicable accrediting agencies as required by the terms of accreditation.
- 2.4.5. The CC is responsible for obtaining informed consent from the donor before undergoing any procedure.

2.5. Marrow Collection Criteria

2.5.1. Collection Center Medical Director

The CCMD shall have at least two years' experience in bone marrow collection or have performed at least ten bone marrow collection procedures.

2.5.2. Anesthesiologist

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

2.5.3. Collection Center Attending Physician

The physician performing the marrow collection shall have performed at least 10 prior collections with at least three collections in the last three years.

2.5.4. Facility Requirements

- A. The CC shall have an experienced team that has performed at least three marrow collections in the past three years.
- 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 leukoreduced 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

The ACMD shall have at least two years' experience in apheresis collections or have performed at least five PBSC collection procedures.

2.6.2. Apheresis Center Physician

- A. A licensed physician qualified by training and experience shall place a central venous line according to WMDA Standards, if determined necessary for the apheresis process.
- B. A licensed physician, with experience in the administration and management of complications is responsible for the administration of mobilizing agents and prescribing home healthcare administration.

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2.6.3. Facility Requirements

- A. The AC shall have an experienced team that has performed at least three apheresis collections in the past year.
- B. The AC shall be registered with the FDA for the apheresis-related activities it performs as part of its contractual agreement with the Registry.
- C. The AC should be accredited by TJC, when possible.
- D. The AC shall have an active IRB-approved protocol for administration of growth factor to healthy unrelated HPC donors and an active IRB-approved protocol for apheresis.
- E. The AC shall maintain written standard operating procedures for peripheral venous access assessment and placement of central venous catheters.
- 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 written agreement(s) which define 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.

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2.9.4. The CC must maintain records for an appropriate period of time, in accordance with WMDA Standards and 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.

3. TRANSPLANT CENTER CRITERIA

3.1. Personnel

3.1.1. Transplant Center Medical Director

- A. The Transplant Center Medical Director shall be board certified (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 had at least two years of experience as an attending physician responsible for clinical management of allogeneic transplant recipients in the inpatient and outpatient settings.

3.1.2. Transplant Center Attending Physician

The transplant medical team shall include at least one board certified physician with a minimum of one year experience in management of transplant recipients, other than the Transplant Center Medical Director.

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.

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.

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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 for at least 10 different patients per year.
- 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.
- 3.3.7. The TC shall maintain written policies, procedures and clinical guidelines for management of allogeneic transplantation.

3.4. Responsibilities

- 3.4.1. The TC shall maintain adequate written policies and procedures relating to its transplant program 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.

4. LABORATORY CRITERIA

- 4.1. Laboratories performing clinical testing for the Registry or for network affiliates shall comply with federal, state and local regulations or international equivalents.
- 4.2. Laboratories shall maintain written procedures for the activities they perform.
- 4.3. Laboratories performing clinical testing for the Registry or for network affiliates shall comply with NMDP standards.
- 4.4. Laboratories performing infectious disease testing, ABO and Rh typing, red cell antibody screening, and other testing shall be accredited by CMS or the CLIA Program of the Health Care Financing Administration.
- 4.5. Laboratories that perform infectious disease testing must use donor screening tests approved, licensed or cleared by the FDA and shall perform such testing in accordance with manufacturer instructions.
- 4.6. Laboratories that perform infectious disease testing shall be registered with the FDA.
- 4.7. Laboratories performing HLA tissue typing shall be accredited by ASHI, EFI and/or CAP or a non-US equivalent.

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- 4.8. Blood banks collecting donor autologous blood shall be licensed or registered with the FDA.
- 4.9. Laboratories processing HPCs for the Registry shall be registered with the FDA.

5. PROCESS REQUIREMENTS AND CRITERIA

5.1. Recruitment Practices

5.1.1. Donor Eligibility and Suitability

- A. Donors shall be between the ages of 18-60 inclusive and in good health in order to join and remain in the Registry.
- B. During the course of any recruitment activities, including initial enrollment, CT, and workup stages, donors shall be medically screened via a health questionnaire by the Registry using current health history guidelines for the purpose of establishing preliminary eligibility and suitability.
- C. Newly recruited donors are HLA-typed by GOL at a laboratory that meets GOL's HLA typing requirements (see Section 4.7.)
- D. Information obtained from the donor during the stages of the recruitment process shall include but is not limited to the following: age, gender, and willingness to donate. The donor also completes a short health history questionnaire.

5.1.2. Donor Education and Informed Consent

- A. Donors shall be provided with educational materials at initial registration and throughout the entire process, including CT and workup stages. Materials used to recruit donors shall provide information on stem cell donation, the risks and benefits associated with the procedures and confidentiality.
- B. Donors shall be informed that their HLA tissue type will be available for search by TCs and CRs anywhere in the world, without discrimination based on any attribute of the patient.
- C. Donors shall be informed that results from recruitment efforts undertaken on behalf of any one patient will be made available to all patients seeking matched unrelated BM/PBSC/T Cell donors, and not exclusively to the patient for whom the recruitment effort is organized.
- D. Donors shall never be coerced to join the Registry.
- E. Donors shall be informed that their role is purely voluntary, and that there is no remuneration for donation, except in the instance of reimbursing for expenses incurred as a result of participation.
 1. In cases of financial hardship, the donor may submit a request for reimbursement of loss of earnings on the days of the Physical Exam and collection.
- F. Donors are permitted to withdraw at any time without prejudice. However, donors are asked to give careful consideration to the decision to participate, so as to avoid giving false hope to patients needing transplants or potentially causing harm to the patient.
- G. Donors shall be educated on the risks associated with engaging in high-risk behavior that may result in infectious disease transmission to a transplant recipient.

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- H. Donors shall be informed of their right to be accompanied by a donor advocate at any point during the donation process.
- I. Donors shall be informed that they do not assume financial liability for any portion of the follow-up testing, stem cell harvest or procurement process.
- J. Donors shall be informed of their right to receive their health history information and test results.
- K. Donors choosing to participate shall acknowledge their understanding of the educational materials by voluntarily completing and signing a form indicating their consent for participation.

5.1.3. Donor Tissue Typing and Quality Control

- A. All donors shall be tissue typed using DNA-based typing techniques at a minimum of HLA A, B, C and DRB1.
- B. Tissue samples shall be collected for subsequent testing, and consent shall be obtained from the donor for this purpose.

5.2. Pre-Donation Stages

5.2.1. Extended Typing

- A. Donors requested for ET shall be contacted and indicate their interest to proceed if identified as a match for a patient needing a transplant, and evaluated for preliminary eligibility and suitability.
- B. If a fresh sample for ET is required from a donor, consent shall be obtained from that donor.
- C. Evaluation of preliminary eligibility and suitability of a donor shall be obtained prior to collection of a fresh sample.
- D. The Registry shall endeavor to send the donor's sample for HLA typing within the timeframe specified by the current WMDA recommendations.
- E. The Health History Questionnaire administered to donors at the ET stage is valid for 90 days.

5.2.2. Confirmatory Typing

- A. Consent shall be obtained from donors who proceed to the CT stage.
- B. Donors shall be provided with educational materials describing the risks and benefits associated with BM/PBSC/T Cell donation.
- C. The Health History Questionnaire administered to donors at the CT stage is valid for 90 days.
- D. Donors shall undergo testing for HLA typing, blood group typing and infectious diseases (IDMs) at the CT stage.
- E. The HLA typing is carried out at a laboratory designated by the TC to confirm the results obtained at initial recruitment.
- F. The Registry shall endeavor to send the donor's sample for HLA typing within the timeframe specified by the current WMDA recommendations.
- G. The IDM testing is carried out at a laboratory that meets the requirements described in Sections 4.4 through 4.6.
- H. IDM test results shall be transmitted to the TC in a timely fashion.
- I. Donors shall be provided with counseling for positive infectious disease test results as specified by applicable federal, state, and local statutes.
- J. Donors with a confirmed positive test for HIV shall not be eligible to donate.

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- K. Donors with a confirmed positive test for relevant communicable disease agents (e.g. HBV or HCV) shall not be eligible to donate unless urgent medical need is documented.

5.2.3. Workup

A. Information Session

1. Donors requested for collection shall participate in a detailed telephone information session to be educated on the risks and benefits associated with the collection process.
2. Following the information session and prior to referral to the CC for the physical exam, the donor shall sign a form indicating intent to donate.

B. Health History Screening

1. The donor shall complete a GOL health history questionnaire.
2. The questionnaire shall ask for all information required by applicable regulatory and accrediting agencies.
3. The DSMD or designee shall review the completed questionnaire to determine whether the donor is preliminarily eligible and suitable to be referred to a CC/AC for a Physical Exam and determination of final eligibility and suitability to donate.
4. The questionnaire is valid for 12 weeks.

C. Physical Examination

1. To determine the eligibility and suitability of the donor before the donation, the CC attending physician shall administer a complete physical examination including all tests required by applicable regulatory requirements, industry standards and network affiliates involved in the donation.
2. The donor shall complete a health history questionnaire administered by the CC. The questionnaire is valid for 12 weeks.
3. The CC shall test for infectious diseases including but not limited to:
 - Hepatitis B
 - Hepatitis C
 - Syphilis
 - HIV 1/2
 - HTLV I/II
 - CMV
 - Chagas
 - WNV
4. Other tests shall include at a minimum urinalysis, a complete blood count, electrolytes and glucose, blood urea nitrogen and creatinine, total serum protein plus albumin or serum protein electrophoresis, ABO and Rh, and screening for Hemoglobin S.
5. A chest x-ray and/or electrocardiogram are carried out at the discretion of the CC physician.
6. The CCAP shall evaluate the donor for the following: pregnancy, recent vaccinations and/or transfusions, past deferral from blood donation, body piercings and tattoos.

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7. The CCAP shall evaluate the donor for physical and emotional conditions that may be contraindicated to bone marrow and PBSC donation or might cause any part of the donation process to jeopardize the health of donor, including but not limited to the administration of anesthesia.
8. The CCAP shall interpret the results of the examination, health screening and tests, and shall transmit the results and interpretation to the Registry, including information about conditions that could jeopardize the safety of the donor and/or the recipient.
 - a. The CCAP shall determine whether abnormal findings constitute unacceptable risk to the donor.
 - b. The CCAP shall counsel the donor on the nature of any abnormal findings, and the donor has the right to decline to donate.
 - c. If the CCAP determines that there is unacceptable risk to the donor or the recipient due to abnormal findings, the CCAP shall designate the donor as ineligible and/or unsuitable.
 - d. Donors evaluated by the CCAP as ineligible might be designated as available in the case of urgent medical need on an exceptional basis as deemed appropriate by the CC.
9. The results of the physical examination are valid for six months.
10. Marrow and PBSC donors shall undergo repeat infectious disease testing if more than 30 days will pass between the Physical Exam and the scheduled donation date.
11. T Cell donors shall undergo repeat infectious disease testing if more than seven days will pass prior to the scheduled donation date.
12. The CCAP performing the donor's physical examination and/or overseeing the collection shall not be the Transplant Center Attending Physician responsible for the care of the recipient.
13. Female PBSC donors shall have repeat pregnancy testing prior to the administration of mobilizing agents.
14. Female marrow/T Cell donors shall have repeat pregnancy testing prior to collection.
15. All female donors shall have repeat pregnancy testing two days prior to collection.

D. Pre-collection Requirements

1. The Registry shall provide medical insurance coverage to BM/PBSC/T Cell donors at the workup stage, including disability and death benefits.
2. The patient shall not begin pre-transplant conditioning until the following conditions have been met:
 - a. Signed verification of the BM/PBSC/T Cell prescription by both the transplant and the collection physician.
 - b. TC has received final clearance reporting results of infectious disease testing, ABO group, Rh type, and other relevant donor information including but not limited to allergies, transfusion history, past pregnancy history, donor's preferred method of stem cell collection (if different than the TC's request) and willingness of donor to donate again if necessary.

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3. BM/PBSC/T Cell prescriptions and verifications of prescription shall provide all information required by the WMDA. This information shall include but is not limited to medium, anticoagulant and additives used during product procurement and transport.
 - a. Marrow prescriptions shall specify the required volume and the nucleated cell count of marrow required.
 - b. PBSC prescriptions shall specify the number of apheresis procedures required, the total number of CD34 positive cells required, and whether or not donor plasma should be added prior to completion of the apheresis procedure.
 - c. T Cell prescriptions shall specify the volume of whole blood to be processed.
4. If the TC requests pre-collection blood samples from the donor, the Donor Services staff shall send the appropriate test tubes to the CC so that the blood can be drawn during the Physical Exam. The Donor Services staff shall ensure that the test tubes arrive at the TC.

5.3. Product Procurement

5.3.1. Bone Marrow

- A. The harvest shall be performed using sterile disposable needles designed specifically for HPC-M collection.
- B. HPC-M shall be taken from the posterior aspect of the pelvic bone (iliac crest) only.
- C. Total volume aspirated shall not exceed 20 ml/kg donor body weight.
- D. The CC shall perform a nucleated cell count to assure the prescribed amount has been procured.
- E. Marrow shall be filtered in accordance with the CC's routine practices, unless otherwise stipulated. The collection shall employ a closed system incorporating the filter.
- F. Anticoagulant shall be added to marrow in sufficient quantities to prevent coagulation during transport.
- G. No additive other than the anticoagulant is to be added to the marrow for transport, unless otherwise instructed in writing by the TC.
- H. HPC-M shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags appropriate for HPC-M collection, each with ports that can be entered aseptically.

5.3.2. Apheresis

- A. Total volume of blood processed shall not exceed 24 liters per donation, unless approved by GOL.
- B. Collection shall be performed using an instrument and software designed for mononuclear cell collection.
- C. Collection shall be performed using ACD-A anticoagulant in a ratio sufficient to prevent extracorporeal clotting.
- D. The Apheresis Center shall obtain component cell counts, including CD34 counts.
- E. Cells shall be suspended in sufficient donor plasma to maintain viability of the cells during transport.

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5.4. Post-Procurement Processing

- 5.4.1. Additional processing such as T-cell or red cell depletion is to be performed by the TC.
- 5.4.2. The CC shall not add anything, process or cryopreserve BM/PBSC/T Cell products except as requested by the TC.

5.5. Preparation for Transport to TC

- 5.5.1. The BM/PBSC/T Cell product bag(s) and related samples being sent to the TC after a collection shall be labeled by the CC/AC in compliance with applicable regulatory requirements and industry standards.
- 5.5.2. Labeling on product bag(s) shall contain the following information: product type; donor identification number; recipient name and identification number; name, address and telephone number of TC; donor ABO group and Rh type; biohazard labeling that conforms to domestic law and international convention; nature of anticoagulant used; total volume collected; additional additives; and collection date and time, including time zone.
- 5.5.3. The following documents and reports shall accompany BM/PBSC/T Cell products: product analysis; final eligibility status of donor prior to collection; infectious disease test results and interpretation; product labeling checklist; circular of information; courier letter; customs declaration (if necessary); and the name, address, telephone and fax numbers of the TC, CC and Registry.

5.6. Packaging and Transportation of BM/PBSC/T Cell Products to TC

- 5.6.1. Product bags are placed in an outer container sealed to prevent leakage of any kind. The second container should be enclosed in a rigid structure with insulating properties. Absorbent material is placed between the primary and secondary receptacles sufficient to absorb the entire contents of the bags in the event of leakage.
- 5.6.2. The product temperature shall remain within the range specified by the TC.
- 5.6.3. The product shall remain in the possession of the courier at all times.
- 5.6.4. The product shall travel in the vehicle's passenger compartment.
- 5.6.5. The courier shall expedite product delivery by arranging transport methods that minimize travel time.
- 5.6.6. The courier shall have backup delivery plans in place.
- 5.6.7. The product should not be exposed to radiation of any kind, specifically x-ray at airports.
- 5.6.8. The courier shall be an experienced traveler carrying photo identification, sufficient cash and credit cards.
- 5.6.9. The facility sending the courier shall train the courier according to applicable regulatory requirements and generally accepted industry standards.

5.7. Follow-up

- 5.7.1. Short-term donor follow-up shall be performed within 48 hours of collection, then at one week and then every week until the donor has fully recovered from the collection process.
- 5.7.2. Long-term donor follow-up shall be performed at one and six months, then again at years 1, 3, 5 and 10 after donation.
- 5.7.3. Recipient follow-up shall be performed by requesting updates on the recipient's status from the TC at one month and six months after transplantation, and then

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annually for five years. For transplants facilitated by the NMDP, the NMDP provides updates at nine months, twelve months, eighteen months and 30 months.

5.8. Subsequent Donation Requests

- 5.8.1. The number of subsequent donations by a donor for the same recipient should not exceed two and only one of these may be HPC (marrow or PBSC). Thus, a donor may donate up to three times for each recipient, but not more than two HPC per recipient.
- 5.8.2. The lifetime maximum for marrow donation is twice.
- 5.8.3. Donations for a third recipient from a given donor will not be permitted.
- 5.8.4. Requests that do not conform to the above points may be submitted for consideration.
- 5.8.5. All subsequent donation requests must be approved by the DSMD.
- 5.8.6. The donor has the right to refuse consent for any subsequent request.

5.9. Management of Adverse Events and Reactions

- 5.9.1. The Registry shall maintain procedures describing how adverse events and reactions are managed, including but not limited to requirements for documentation, investigation, evaluation and reporting.
- 5.9.2. Adverse events shall be reported in accordance with applicable regulatory requirements and generally accepted industry standards.

5.10. Confidentiality Practices

- 5.10.1. All donor and recipient identification information shall be provided on a need-to-know basis to authorized personnel only, conforming to the most restrictive applicable regulatory requirements and standards governing the protection of such information.
- 5.10.2. All donors and recipients shall only be identified by unique proprietary identification numbers, unless the name is required to be entered on a form or label.
- 5.10.3. Donors shall be informed that the donation process is anonymous.
 - A. Only recipient age, sex and diagnosis may be revealed to the donor.
 - B. Geographic location, nationality, ethnicity and racial background shall not be revealed.
 - C. Donor and recipient may correspond anonymously through the Registry, unless any aspect of the search, donation, and/or transplant process has taken place in countries where such correspondence is prohibited by law or policy.
 - D. The donor and recipient may meet by mutual written agreement, but not less than one year after the anniversary date of the transplant, unless any aspect of the search, donation, and/or transplant process has taken place in countries where such a meeting is prohibited by law or policy.
- 5.10.4. Under no circumstances will the contents of a donor's demographic profile be released without the express written permission of the donor and in accordance with Donor Services procedures.

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- 5.10.5. Donor medical information is considered strictly confidential, except in cases when infectious disease testing reveals conditions that require notification of local health departments. Even then, only donor demographic and infectious disease test results shall be released to the local health departments as mandated by their regulatory requirements.
- 5.10.6. Donor medical information shall be used solely for the purposes of (1) listing the donor's HLA tissue typing in the registry, making the donor available anonymously for search by TCs and CRs; (2) establishing donor eligibility and suitability.
- 5.10.7. Donor and recipient records shall be available for inspection by representatives of authorized regulatory and accrediting agencies upon verification of the representatives' credentials.

5.11. Establishment and Maintenance of Affiliate Certification and Accreditation

- 5.11.1. If a CR or TC applies to the Registry to request access to search the Registry's donor database for the first time, Registry administration shall ensure that the CR or TC meets participation criteria prior to granting access.
- 5.11.2. If the Registry is entering into a new contractual agreement with a CC or AC, Registry administration shall determine whether the CC or AC meets relevant participation criteria.
- 5.11.3. The Registry shall monitor the status of applicable affiliate certifications, accreditations, licenses, and registrations.

5.12. Insurance

All network affiliates shall carry liability insurance with minimum limits that meet requirements established by Gift of Life administration.

5.13. Document and Record Management

- 5.13.1. The Registry shall utilize a document control process that complies with applicable regulatory requirements and industry standards.
- 5.13.2. All documentation related to donors and patients shall be maintained indefinitely. This includes documentation related to preliminary and formalized searches.
- 5.13.3. All electronic and hard copy files shall be secured and access limited to authorized personnel only.
- 5.13.4. Records shall be maintained in a way to ensure their integrity and preservation for the duration of the defined retention period and be retrievable.
- 5.13.5. The Registry shall include appropriate methods of protecting records in any disaster planning and business continuity document.
- 5.13.6. All forms and documents used to communicate with external entities should contain current Registry address and phone information.
- 5.13.7. Records shall be created concurrently with the performance of each critical activity. The work performed, the individual performing the work, and when it was performed shall be identified.
- 5.13.8. Records shall be legible, indelible, complete and retrievable in a reasonable period of time.
- 5.13.9. Records shall be preserved and protected from accidental or unauthorized destruction or modification.

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5.14. Financial Responsibility

- 5.14.1. Financial responsibility for the donor search, testing and collection processes shall be determined in advance of rendering services.
- 5.14.2. Terms of payment shall be clearly established in writing with the TC or CR.
- 5.14.3. Current fee schedules shall be provided to TCs and CRs, and 30 days notice shall be provided upon revision.
- 5.14.4. Any cost not standardized or, for any reason, not accessible through such a schedule (e.g. courier charges) should be estimated and communicated in advance to the CR and/or the TC.
- 5.14.5. If the collection procedure is cancelled after the final donor selection, the Registry is entitled to charge for services performed prior to notice of cancellation. This practice must be noted on the fee schedule.
- 5.14.6. The Registry providing donor stem cells or any other requested service should bill the TC or CR within 30 days of service.
- 5.14.7. A CR requesting a service for a patient or forwarding such a request from a TC guarantees the payment of completed services. If the CR cancels the service, the Registry shall expect full payment provided that the services are completed and reported within 30 days of the cancellation date.

5.15. Contractor Engagements

- 5.15.1. All entities working as contractors for the Registry shall comply with applicable regulatory requirements and industry standards.
- 5.15.2. Contractors shall sign confidentiality agreements and conflict of interest statements as deemed necessary.

5.16. Business Continuity and Disaster Planning

The Registry shall have a plan to protect records, facilities, and personnel during and after a disaster, as well as a plan describing how to operate under emergency conditions, and how to resume full operations as conditions improve.

5.17. Communication of Changes to Regulatory and Accrediting Agencies

Upon a significant reorganization, a change in key personnel, or any other major change in infrastructure, the Registry shall notify all applicable regulatory and accrediting agencies.

5.18. Participation in Research

Should the Registry participate in research, such participation shall conform to all federal regulatory requirements for the protection of human subjects.