

Criteria for Donor Registries

1.0 General

- The registry shall have non-profit status.
- The registry shall have knowledge and experience in the coordination of the international search process with experienced staffing for the coordination of patient-specific donor testing, blood sample shipment, stem cell collection and the transportation of stem cell products.
- The registry staff shall have knowledge and experience in the management of volunteer cellular donors, apheresis and marrow donation, donor education, donor counseling, confidentiality issues, testing, and medical evaluation of the donor.
- The registry shall provide comprehensive patient advocacy, separate from donor advocacy.
- The registry shall provide comprehensive donor advocacy, separate from patient advocacy.
- The registry shall have knowledge of patient needs, patient educational resources and patient confidentiality issues.
- The registry shall maintain the confidentiality of donors and patients.
- The registry shall be responsible for obtaining informed consent throughout the entire search, recruitment and donation process.
- The registry shall maintain collaborative relationships with registries, transplant centers, laboratories, collection and apheresis centers to ensure uninterrupted operations throughout the search process.
- The registry shall maintain a comprehensive search program with an up to date search algorithm.
- The registry shall utilize all available electronic communications tools for the automated exchange of search data.
- The registry shall have adequate professional and general liability insurance.

Criteria for Donor Registries

2.0 Adequate Staffing

- The registry shall have a chief medical officer / medical director with demonstrated experience in patient care, the management and counseling of donors, confidentiality issues, and medical screening and donor work up for cellular donation.
- The chief medical officer / medical director shall be responsible for reviewing donor medical evaluations and utilizing knowledge as a physician to identify possible risks to both donor and patient in order to determine donor eligibility and suitability.
- The chief medical officer / medical director shall interact with patients, donors and transplant and collection physicians when necessary.
- The registry shall have a medical advisor who is a licensed physician knowledgeable in the field of cellular therapy transplantation.
- The registry shall have a medical review board of qualified individuals with adequate training in cellular therapy transplantation or a related field.
- The registry shall have a competent scientific advisor with knowledge of histocompatibility.
- The registry shall have adequate staffing to provide both comprehensive donor and patient services.
- The registry shall maintain dedicated Information Systems staffing.

3.0 Adequate Facilities

- The registry must have a fixed physical site with sufficient office space so that all work can be carried out in an environment designed to minimize errors and maintain confidentiality.
- The registry shall have adequate computer systems for data management and the exchange of information, a staffed telephone during regular business hours, fax and e-mail capabilities.
- The registry shall have adequate staff to assume the volume and variety of services required of donor search, donor recruitment, donor testing, donor physical examination and stem cell collection, file maintenance, and timely search response as defined by the WMDA as well as cover for emergencies.

Criteria for Donor Registries

4.0 Compliance

- The registry shall maintain evidence of affiliate compliance with approved, licensed or certified organizations in accordance with United States Federal laws and regulations (or non-U.S. equivalent):
 - An HLA typing laboratory accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), or the European Federation for Immunogenetics (EFI), or similar organization for non-U.S. laboratories.
 - A laboratory certified by the Clinical Laboratory Improvement Amendments program (CLIA), or a non-U.S. equivalent for infectious disease markers and other tests defined by international recommendations and regulations.
 - A laboratory (certified by AABB or CLIA, or non-U.S. equivalent) for ABO/Rh typing and testing for unexpected antibodies to red cell antigens.
 - A Blood Bank registered by the U.S. Food and Drug Administration (FDA) or non-U.S. equivalent for collection of autologous whole blood units.
 - An Apheresis and/or Collection Center that is registered with the FDA and is accredited by FACT and /or NMDP with access to additional physical exams providers as needed.
 - Physicians who perform donor physical examinations must be associated with a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

5.0 Advocacy

- Patient and donor advocates shall be readily available. Separate advocates must be utilized for patients and donors.
- The registry must ensure availability of emergency coverage and a 24 hour number to meet emergent patient and donor needs.

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6.0 Written Standards

- The registry shall maintain complete and detailed written standards and procedures that are updated annually, at a minimum, with dedicated quality assurance staff.
- The registry will adhere to World Marrow Donor Association (WMDA) guidelines and standards.