

Criteria for Affiliated Donor Registries

1.0 General

- The Registry shall have status as a non-profit organization.
- The Registry 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 be responsible for obtaining informed consent, providing an adequate medical evaluation and testing of the donor, and informing the donor of the risks involved in cellular donation.
- The Registry shall have adequate professional and general liability insurance.
- The Registry shall utilize adequate procedures to maintain the confidentiality of donors and patients.

2.0 Adequate Staffing

- The Registry shall have a medical director with demonstrated experience in the management and counseling of donors, confidentiality issues, and medical screening and donor work up for cellular donation.
- The Registry shall have a medical director who is a licensed physician knowledgeable in the field of cellular therapy transplantation.
 - The 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.
- 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.

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.

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- 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 recruitment, donor follow up, donor work up, file maintenance and timely search response as defined by the WMDA as well as cover for emergencies.

4.0 Access to Adequate Facilities

- The Registry shall have access to the following facilities approved, licensed or certified in accordance with United States Federal laws and regulations (or non-U.S. equivalent):
 - A 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.

5.0 Donor Advocate

- The services of a donor advocate shall be made available to all donors.

6.0 Written Standards

- The Registry shall adhere to CRIR's written standards for every aspect of the management of donors.
- The Registry must maintain and make available written policies and procedures of operation upon request.