

Criteria for Affiliated Apheresis Collection Centers

1.0 General

- The center shall be responsible for the collection of cellular products (stimulated stem cells or unstimulated peripheral blood lymphocytes).
- The center must be licensed and/or registered with the FDA Non-U.S. Apheresis Collection Centers must be in compliance with appropriate laws and regulations of the country in which the center is located.
- U.S. centers must meet applicable Good Manufacturing Practices (GMP) and Good Tissue Practices (GTP).
- The center must maintain standard operating procedures G-CSF administration, stem cell collection, management of adverse events, the proper handling and processing of collected products
- The center must maintain written procedures for maintenance of all apheresis equipment.
- The center shall have experience in apheresis collection and must have performed at least 3 collections by apheresis within the past year.
- The center shall have a policy for emergency care.
- The center must have adequate general and professional liability insurance.
- Any significant changes to the center's team (including management, physician or coordinators) must be reported to the Caitlin Raymond International Registry (CRIR) within 30 days.
- Any change in the center's registration or accreditation status must be reported to CRIR immediately.

2.0 Adequate Staffing

- The center must have a qualified medical director who is a licensed physician with adequate training and experience.
 - The center's medical director shall have at least one years experience in the collection procedure.

Criteria for Affiliated Apheresis Collection Centers

- The center's medical director and the physician performing the work up are responsible for reviewing donor medical evaluations and determining risk to patients and donors.
- The center's medical director and the apheresis center physician shall be responsible for protecting the safety of the donor, the safety of the collected product(s), as well as for identifying conditions in the donor that may be transmissible by transfusion or transplantation.
- A licensed, trained physician must be responsible for supervising the administration of G-CSF and be available throughout the administration process, as well as during and after the collection.
 - The responsible physician must be qualified by knowledge and training in the administration of G-CSF and monitoring the effects on donors and/or patients.
- A licensed, trained physician, qualified by training and experience shall place central venous catheters, when necessary.
 - The center shall have collection staff experienced in the management and care of central venous catheters.
- The center shall have staff experienced in apheresis procedures.
 - Experience must include, at a minimum, handling, processing and labeling of apheresis products.
 - Cellular product labels and tie tags are provided by CRIR.
 - The center physician(s) shall have sufficient training and experience with apheresis collection procedures.
 - Physicians supervising collection shall have at least one year of experience in the collection procedure.

3.0 Adequate Facilities

- The center must have a fixed physical location for the coordination of collection activities.
- The center shall indicate the days and hours it is available for collections.

Criteria for Affiliated Apheresis Collection Centers

- Collections requiring more than one collection day must be accommodated.
- The center shall have adequate computer resources for data management, a staffed phone during regular business hours, fax, and e-mail capabilities.
- The center shall have appropriate apheresis equipment, supplies and pharmaceuticals.
- The center must maintain internal auditing and corrective action plans and must maintain a quality plan that meets applicable GMP/GTP requirements.

4.0 Access to Adequate Facilities

- The center 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 laboratory certified by the Clinical Laboratory Improvement Amendments program (CLIA), or a non-U.S. equivalent.
 - A hospital accredited by one of the following: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), or non-U.S. equivalent.
- The center must have access to facilities licensed, certified or accredited in accordance with U.S. laws (or non-U.S. equivalent) that enable them to provide the following:
 - Monitor and report donor blood and component counts.
 - Perform CD34+ cell counts of donor's peripheral blood, as well as the collected product, if necessary.
 - Perform donor ABO and Rh typing.
 - Perform or obtain Infectious Disease Marker (IDM) testing via an IDM laboratory that meets all FDA requirements for such testing.

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5.0 Patient/Donor Safety and Confidentiality

- The center shall be responsible for protecting the safety and confidentiality of the donor.
- The donor must be evaluated by a physician to determine if he/she is an acceptable candidate.
 - For Registry donors, the results of this evaluation shall be reviewed and approved by CRIR's Medical Director prior to final donor clearance.
- Both the apheresis center and the donor center shall ensure that conditions, which may be transmissible by blood, are identified in the donor in order to protect the safety of the patient.
 - A physician shall be made available for the duration of apheresis collection and for follow-up.
 - The center shall have 24 hour support services available.

6.0 Written Standards

- The center shall maintain written policies and procedures for all aspects of apheresis collection. These procedures shall be made available to CRIR and shall be consistent with appropriate U.S. regulations or the laws and regulations of the country in which the center is located (for centers located outside of the U.S.).
- The center shall maintain and make available written standard operating procedures upon request.
- The center shall have mechanisms in place to protect the privacy of potential donors, donors, and patients.
- The center shall provide documentation annually, at a minimum, that they continue to meet these criteria. Significant changes in personnel, facility or support services shall be reported promptly to the Registry.
- The transplant center shall adhere to The Registry's written standards.