

Criteria for Cord Blood Programs

1.0 General

- The cord blood program shall have experience in the recruitment and management of cord blood collections, donor education, donor counseling, confidentiality issues, and medical evaluation.
- The cord blood program shall abide by national/international regulations from the FDA or non-U.S. equivalent and should adhere to recommendations from the WMDA.
- The cord blood program shall have adequate professional and general liability insurance.

2.0 Adequate Staffing

- The cord blood program must have a medical director who is a licensed physician who:
 - Is trained in the field of cellular therapy transplantation or has received post-doctoral training in a related field.
 - Is responsible for the evaluation and follow up of the potential donor; protocols for informed consent; and protocols for the collection, processing, testing, banking, selection and release of the cord blood unit.
- The cord blood program must have a scientific advisor highly competent in human histocompatibility with sound knowledge of histocompatibility nomenclature.
- The cord blood program should have a medical review panel.
- The cord blood program must have adequate staffing and resources to assume the volume and variety of services required, including staff coverage for emergencies.
- The cord blood program staff shall be adequately trained and competent personnel to perform processing, cryopreservation, storage and retrieval of cord blood units and samples
- The cord blood program must provide daily and emergency coverage.

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3.0 Adequate Facilities

- The cord blood program 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 cord blood shall have a secure information management system for the management of cord blood donations and the exchange of information, a staffed telephone during regular business hours, fax and e-mail capabilities.

4.0 Access to Adequate Facilities

- The cord blood program 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.
 - Cord blood collection centers that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), or comparable non-U.S. accreditation.
- The cord blood program shall have adequate and appropriate resources to support its activities.
- The cord blood program shall use adequate and secure facilities for processing, storing and retrieving cord blood units and samples.
- The cord blood program shall use a secure environment for confidential record storage.

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- The cord blood program must document staff and volunteer training, continuing education and continued competency.

5.0 Confidentiality

- The cord blood program shall be responsible for the collection and maintenance of all identifying data related to the cord blood unit.
- The cord blood program shall ensure patient and donor confidentiality and use adequate means to protect identifying data.

6.0 Written Standards

- All cord blood units intended for use in unrelated donor transplantation must:
 - Be typed for HLA-A, B (serology or DNA-based) and DRB1 (DNA-based);
 - Be typed for ABO group and Rh type;
 - Be negative for microbial contamination;
 - Be labeled appropriately to permit traceability, including the date of collection;
 - Be collected and stored in accordance with the Standards of AABB or the Foundation for the Accreditation of Cellular Therapy (Netcord/FACT);
 - Have at least two segments each containing at least 100 uL at the time of cryopreservation available for additional testing of DNA, viability, microbial contamination, or another assay as required by the NMDP;
 - Have results available on the maternal infectious disease testing;
 - Have record of a maternal medical history prior to or within 30 days following the collection of the unit;
 - Must have all records reviewed by the Medical Director or designee prior to listing the CBU with the CRIR and re-evaluated prior to the release of the CBU for infusion;
 - Have the volume and nucleated cell count documented;

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- Have been collected for the purpose of transplantation; and
- Not be stored with non-human sources or blood components.

- The cord blood program shall maintain written standards for every aspect of cord blood banking, including the recruitment and screening of the mother and donor, testing requirements and criteria for inclusion within the cord blood bank inventory
- The cord blood program must provide CRIR with a copy of their standards and procedures as well as accreditation and certification documents yearly, at a minimum.
- Significant procedural changes, especially those that may affect the search and procurement process shall be reported to CRIR as soon as possible.
- The cord blood program shall adhere to CRIR's written standards.