

## **Criteria for Affiliated 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.
- 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 staff must be adequately trained to perform necessary duties.

### **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 adequate computer systems for the management of cord blood donations and the exchange of information, a staffed telephone during regular business hours, fax and e-mail capabilities.

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### **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.

### **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**

- The cord blood program shall maintain written standards for every aspect of cord blood banking.
- 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 effect 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.