CORD BLOOD COLLECTION, BANKING, AND RELEASE FOR ADMINISTRATION

DOCUMENT SUBMISSION REQUIREMENTS

NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration

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Foundation for the Accreditation of Cellular Therapy (FACT)
CORD BLOOD
DOCUMENT SUBMISSION REQUIREMENTS

The volunteer inspectors who will be inspecting your Cord Blood Bank (CBB) will prepare for your inspection by reviewing information and documents you submit before your inspection is scheduled. The following is a list of information and documents you must submit to assist the inspectors in their preparation for the inspection.

Copies of the following items are required prior to scheduling the on-site inspection, and must be uploaded via the online Compliance Application within the FACT accreditation portal. Please label all uploaded electronic files with a title, such as "Physical Floor Plan" or "Informed Consent Form." Do not use patient names on the documents submitted.

The documents listed in the following pages are only a subset of what inspectors will need to review. Documentation of compliance with each standard must be readily available to the inspectors during the on-site inspection. Those items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency. See the Applicant Guidelines on the FACT website at www.factwebsite.org for tips on how to prepare on-site documentation.

The international inspection teams use English as the common language; therefore, all submitted documents, policies, and procedures must be in English unless otherwise specified.

For additional information on the required documents listed below, see the referenced standard and the accompanying information in the Accreditation Manual.

**TABLE OF CONTENTS**

General Cord Blood Bank Documentation ........................................................................................................ 2

Key Personnel Documentation ............................................................................................................................. 5

Policies and Standard Operating Procedures Documentation ......................................................................... 7

On-Site Electronic Record System Documentation .......................................................................................... 9

HRSA- Specific Criteria Documentation ......................................................................................................... 9

Educational Activities Form ............................................................................................................................... 10

Critical Electronic Record Systems Form ....................................................................................................... 11
GENERAL CORD BLOOD BANK DOCUMENTATION

- Completed Facility Site Grid. [B1.1]

- A copy of the license, registration and/or accreditation certificate from the appropriate governmental authority for the activities performed (for example, in the U.S.A., the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products [Form FDA 3356]). If the license/registration/accreditation certificate is in a language other than English, include a general description of the document in English. [B1.2.1 and D1.1]

- Samples of educational, promotional, or recruitment materials used. [B1.6]

- Supporting evidence of claims not currently supported by scientific evidence. This must be in English. [B1.6]

- List of all participating facilities and services including, at a minimum, Cord Blood (CB) Collection Sites, CB Processing Facilities, information technology services, testing laboratories, storage facilities, registries and outcomes databases. [B2.3]

- Cord Blood Bank Quality Management Plan that describes the Quality Management Program. [B2.2]

- Organizational chart of all key positions, functions, and interactions within the CBB, the CB Collection Site(s), and the CB Processing Facility(ies). Include at least the name and title of the CBB Director, CBB Medical Director, CB Collection Director(s), CB Processing Facility Director(s), and Quality Unit Manager, including the reporting structure for healthcare professionals performing collections at non-fixed collection sites, if applicable. [B2.3.1]

- Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed under B2.11.3 must be included. [B2.11.1]

- The policy or procedure for qualification of critical vendors, equipment, supplies, reagents, and facilities used for critical procedures. [B2.13]

- The policy or procedure for the validation of critical procedures. [B2.14]

- A copy of the HLA laboratory's current ASHI, EFI, or other appropriate accreditation certificate, submit documentation of certification for DNA-based typing. [B5.6]
  - For ASHI accreditation:
    - Include the accreditation letter in addition to the certificate.
    - If the laboratory is not ASHI-accredited for HSC/BM transplantation, include documentation of HLA expertise available within the Cord Blood Bank for selecting the best matched donor for the recipient.

- Documentation demonstrating that the HLA laboratory has agreed to provide HLA services. [B5.6]
- Examples of all labels. (Complete the labels as you would for use on a cord blood unit.) [B6.6 and Appendices II and III]
  - Partial label.
  - Label at completion of collection.
  - Label at completion of processing and prior to cryopreservation.
  - Label at distribution to a clinical program.
  - Label(s) used on outer containers for transport or shipping from collection.
  - Label(s) used on outer containers at distribution to a clinical program.
  - Biohazard and warning labels and documentation of when they are used.

- Documentation provided to the CB Collection Site(s) that outlines requirements for complying with CBB collection policies and Standard Operating Procedures. [C1.2]

- Copy(ies) of the written agreement(s) between the CBB and the collection site(s). For Cord Blood Banks with fixed collection sites, submit copy(ies) of the written agreement(s) between the bank and the collection site(s). For Cord Blood Banks with non-fixed collection sites, submit an example or template in English of the written agreement(s) used. For Cord Blood Banks with fixed and non-fixed collection sites, submit both types of documentation listed above. [C1.2]

- Instructions sent to collection sites or maternal donors with CB collection kits. If the instructions are in a language other than English, submit at a minimum a summary of the instructions. [C1.9]

- A description of the process for documenting collecting health care professionals' training. [C2.3.2]

- Unsigned example or template of all informed consent forms or agreements. [C4.1]

- Procedure for obtaining informed consent or agreement to collect and bank a CB unit. [C4.1]

- Physical floor plan or diagram of the CB Processing Facility(ies). Label all areas of the plan or diagram that are used for cord blood reception, data entering, processing, cryopreservation, and storage. If the floor plan or diagram is labeled in a language other than English, include a general description. [D1.2]

- The Standard Operating Procedure for validations. [B2.14]

- A list of validations performed of critical procedures. Validations should be available on-site. [B2.14.2.1]

- For each of the validation studies below, submit 1) a validation plan, 2) number of data points used, 3) acceptance criteria, 4) summary of results and conclusion, and 5) review and approval of the plan, results, and conclusion:
  - Collection procedure. [C6.3.3]
  - Processing procedure. [D3.2.4]
  - Cryopreservation procedure. [D3.2.4]
  - Shipping container from collection to processing (only if continuous temperature monitoring is not used). [C7.5.3]

- Document that defines requirements for CB unit specifications. [Appendix V and D8.2]

- A description of the CB unit information sent to the Clinical Program at the time of selection for administration. [E3.3]
If a document other than the current version of the inter-organizational *Circular of Information for the Use of Cellular Therapy Products* is used at your CBB, submit the document made available to the CBB containing the following information:

- Use, indications, contraindications, side effects, hazards, dosage and administration recommendations.
- Instructions to minimize contamination.
- Appropriate warnings related to prevention of transmission of communicable diseases.
- Instructions for handling, thawing, and using the CB unit (including short-term storage and preparation for administration). [E4.5]

Documentation that accompanies a CB unit at distribution or an SOP that outlines accompanying documentation. [E4.6 and Appendix III]

**KEY PERSONNEL DOCUMENTATION**

- **Cord Blood Bank Director** [B1.5 and Appendix I]:
  - Documentation of an earned doctoral degree in medicine or in a related scientific field. If the Cord Blood Bank Director is a licensed physician, a medical license may serve as documentation. If the documentation is in a language other than English, include a general description of the document.
  - Summary of the Cord Blood Bank Director’s education, experience, and job responsibilities that includes the following:
    - Training and a minimum of two (2) years of experience in immunogenetics of transplantation, basic or clinical immunology, immunohematology, basic or clinical hematology, transfusion medicine, blood or tissue banking, or cryobiology.
  - Current responsibilities at the Cord Blood Bank.
  - At least 10 hours annually of continuing education related to the field of CB banking or cellular therapy product collection, processing, and administration since the previous accreditation date. Complete and upload the *Educational Activities Form* (Page 10) or submit other documentation that contains the equivalent information for each activity:
    - Date of activity.
    - Title of activity.
    - Type of activity (for example, webinar, meeting, grand round).
    - Topic of activity (for example, hematology, cell transplantation).
    - Approximate number of hours of activity.

- **Cord Blood Bank Medical Director** [B1.5 and Appendix I]:
  - Current Medical License. If the license is in a language other than English, include a general description.
  - Summary of the Cord Blood Bank Medical Director’s education, experience, and job responsibilities that includes the following:
    - Training and experience in hematopoietic cell transplantation or blood or tissue banking.
    - Current responsibilities at the Cord Blood Bank.
At least 10 hours annually of continuing education related to the field of donor safety, CB banking, or cellular therapy product collection, processing, and administration since the previous accreditation date. Complete and upload the Educational Activities Form (Page 10) or submit other documentation that contains the equivalent information for each activity:

- Date of activity.
- Title of activity.
- Type of activity (for example, webinar, meeting, grand round).
- Topic of activity (for example, hematology, cell transplantation).
- Approximate number of hours of activity.

Cord Blood Collection Director [B1.5 and Appendix I]:

- Summary of the Cord Blood Collection Director’s education, experience, and job responsibilities that includes the following:
  - Bachelor’s Degree. If the documentation is in a language other than English, include a general description.
  - Training and experience in hematopoietic cell transplantation, blood and tissue banking, or CB collection.
  - Current responsibilities at the Cord Blood Bank.
- At least 10 hours annually of continuing education related to the field of donor safety, CB banking, or cellular therapy product collection, processing, and administration since the previous accreditation date. Complete and upload the Educational Activities Form (Page 10) or submit other documentation that contains the equivalent information for each activity:
  - Date of activity.
  - Title of activity.
  - Type of activity (for example, webinar, meeting, grand round).
  - Topic of activity (for example, hematology, cell transplantation).
  - Approximate number of hours of activity.

Cord Blood Bank Processing Facility Director [B1.5 and Appendix I]:

- Documentation of relevant doctoral degree. If the degree is in a language other than English, include a general description.

- Summary of the Cord Blood Processing Facility Director’s education, experience, and job responsibilities that includes the following:
  - Training and experience for the scope of activities carried out in the CB Processing Facility.
  - Current responsibilities at the Cord Blood Bank.
- At least 10 hours annually of continuing education related to the field of CB banking or cellular therapy product collection, processing, and administration since the previous accreditation date. Complete and upload the Educational Activities Form (Page 10) or submit other documentation that contains the equivalent information for each activity:
  - Date of activity.
  - Title of activity.
  - Type of activity (for example, webinar, meeting, grand round).
  - Topic of activity (for example, hematology, cell transplantation).
  - Approximate number of hours of activity.
Quality Unit Manager [B1.5 and Appendix []:

- Quality Unit Manager job description. This must be in English.
- Summary of the Quality Unit Manager’s education, experience, and job responsibilities that includes the following:
  - Relevant training in quality management.
  - Current responsibilities at the Cord Blood Bank.
  - At least 10 hours annually of continuing education related to the field of quality management, CB banking, or cellular therapy product collection, processing, and administration since the previous accreditation date. Complete and upload the Educational Activities Form (Page 10) or submit other documentation that contains the equivalent information for each activity:
    - Date of activity.
    - Title of activity.
    - Type of activity (for example, webinar, meeting, grand round).
    - Topic of activity (for example, hematology, cell transplantation)
    - Approximate number of hours of activity.

POLICIES AND STANDARD OPERATING PROCEDURES DOCUMENTATION

Reminder: All submitted documents, policies, and procedures must be in English unless otherwise specified.

- Table of Contents from the CBB Standard Operating Procedure Manual(s) that includes the title and identifier for each policy and procedure. [B3.2.1]

- Specific policies and Standard Operating Procedures. Label each submitted policy or procedure with the applicable Standard number(s).

For Cord Blood Banks that use an ISO 9000 system of quality management, the required procedures that need to be submitted are usually classified as Level 3 work or job instructions, especially for activities such as collection, processing, cryopreservation, labeling, selection. However, policies or procedures explaining general Quality Management issues may be Level 1 or Level 2 documents.

- Preparation, approval, implementation, review, revision, and archival of all controlled documents (also referred to as an SOP describing the process of writing SOPs). [B2.7.2]

- Donor recruitment and education. [B3.1.1 and C3.1.1]

- Maternal screening and testing (including interpretation and acceptable results). If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a summary of the policy and/or procedure. [B3.1.2]

- Informed consent. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.3 and C3.1.3]

- Suitability assessment of maternal and infant donor. [B3.1.4 and C3.1.4]

- Donor eligibility criteria and determination. [B3.1.5]
- Documentation of infant donor health at birth. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a summary of the policy and/or procedure. [B3.1.7 and C3.1.6]

- Collection of CB units, associated samples, and maternal samples, including processes for both fixed and non-fixed collection sites as applicable. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.10 and C3.1.8]

- Transport and/or shipping of the CB unit, associated samples, maternal samples, and completed records to the CB Processing Facility for both fixed and non-fixed collection sites. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.13 and C3.1.13]

- Labeling of the CB unit, samples, and records at the CB Collection Site, at the CB Processing Facility, and at release for administration. [B3.1.14, C3.1.10, and D2.1.4]

- Acceptance criteria for CB unit receipt, processing, cryopreservation, and storage. [B3.1.15 and D2.1.1]

- CB unit processing and cryopreservation. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a summary of the policy and/or Standard Operating Procedure. [D3.2.4]

- Communicable disease testing, microbial cultures, hemoglobinopathy testing, and other testing. Acceptance criteria for test results must be defined. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.19 and D2.1.7]

- Criteria for release of CB units from quarantine, including nonconforming CB units. [B3.1.21 and D2.1.8]

- Criteria for qualification and listing of CB units for search and administration. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.22]

- Listing, search, selection, reservation, release, exceptional release, and distribution of CB units. [B3.1.23, B3.1.24 and E1.2.1]

- HLA typing including requirements for resolution, loci, timing, and verification. [B3.1.25 and D2.1.9]

- Collection and analysis of transplant outcome data. If the policy and/or Standard Operating Procedure are in a language other than English, submit at a minimum a flow chart of the process. [B3.1.28]

- Current list of critical electronic record systems under the control of the CBB. Complete and upload the Critical Electronic Record Systems form (Page 11) or submit other documentation that contains the equivalent information for each critical record system. [B11.9.1]
Electronic Record System Documentation:

If an electronic record system is used, documentation of validation of the system must be available on-site in addition to a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following NetCord-FACT Standards:

- Validated procedures for and documentation of: [B11.9.6.1]
- Systems development including the verification of calculations and algorithms [B11.9.6.2]
- Numerical designation of system versions, if applicable [B11.9.6.3]
- Prospective validation of system, including hardware, software, and databases [B11.9.6.4]
- Installation of the system [B11.9.6.5]
- Training and continuing competency of personnel in system use [B11.9.6.6]
- Monitoring of data integrity [B11.9.6.7]
- Back-up of the electronic records system on a regular schedule [B11.9.6.8]
- System maintenance and operations [B11.9.6.9]

HRSA-Specific Criteria Documentation:

CBBs participating in the United States National Cord Blood Inventory (NCBI) administered by the Health Resources and Services Administration (HRSA), must submit the following documentation:

- Food and Drug Administration (FDA) observations (Form FD-483(s), List of Observations) received if any in the past 24 months. [1.a]
- Copy of the Cord Blood Bank’s response(s) to the FDA’s observations, if applicable. [1.b]
- Documentation of the Cord Blood Bank’s notification to HRSA of each FD-483 issuance, if applicable. [1.c]
Educational Activities Form

This form is provided as a tool for documenting participation in continuing education. The following information for educational activities completed by key personnel during the current accreditation cycle must be provided to FACT prior to an on-site inspection. A completed form or equivalent documentation is acceptable so long as all information below is included. Specific continuing education requirements for key personnel are listed in the current editions of the applicable FACT Standards.

Name: 

Position: 

<table>
<thead>
<tr>
<th>Date of Activity</th>
<th>Title of activity</th>
<th>Type of activity (e.g., webinar, meeting, grand round, etc.)</th>
<th>Topic of activity (e.g., hematology, cell transplantation, etc.)</th>
<th>Approximate number of hours of activity</th>
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6.6.008 Form 2, Educational Activities Form, Rev. 0
<table>
<thead>
<tr>
<th>Name of System</th>
<th>Description</th>
<th>Document Type (e.g., Excel, custom software, etc.)</th>
<th>Used in Lieu of Paper</th>
<th>Used to Make Decisions</th>
<th>Used to Perform Calculations</th>
<th>Used to Create and/or Store Information Used in Critical Procedures*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example Engraftment Database</td>
<td>Recording and reporting of cell dose and engraftment data</td>
<td>custom software developed in-house</td>
<td>No - processing record is official record</td>
<td>Yes - used for outcome analysis</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Critical procedures include collection procedures, processing techniques, cryopreservation procedures, labeling, storage conditions, and distribution.