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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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. Items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency. Refer to the FACT Accreditation Process Requirements Checklist on the FACT website at www.factglobal.org for tips on how to prepare on-site documentation.

FACT's international inspection teams use English as the common language; therefore, all submitted documents, policies, and Standard Operating Procedures must be in English unless otherwise specified. If a license, registration, certificate, floor plan, label, or other document is in a language other than English, also submit a translation of the document in English.

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

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GENERAL CORD BLOOD BANK DOCUMENTATION

- ❑ Completed Cord Blood Bank 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 USA, the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products). If the license/registration/accreditation certificate is in a language other than English, also submit a translation of the document in English. [B1.3.1 and D1.1]

- ❑ Educational, promotional, and recruitment materials. [B1.2]

- ❑ Cord Blood Bank Quality Management Plan that describes the Quality Management Program and must include a 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. [B2.2 and B2.3]

- ❑ 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, and the reporting structure for healthcare professionals performing collections at non-fixed collection sites, if applicable. [B2.3.1]

- ❑ Written agreement(s) between the CBB and the collection site(s), including instructions sent to collection sites or maternal donors with CB collection kits. [B2.4, C1.2]
  - ❑ For fixed collection sites, submit copy(ies) of the written agreement(s) between the bank and the collection site(s).
  - ❑ For non-fixed collection sites, submit copy(ies) of the written agreement(s) between the bank and the maternal donor, or if applicable, health care professional.

- ❑ Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. [B2.11] At a minimum, the following audits must be included:
  - ❑ Audit of key CBB functions, records and assessment of record review to identify recurring problems, potential points of failure, and need for process improvement. [B2.11.4.1]
  - ❑ Audit of external facilities that perform critical contracted services to verify that these facilities have met the requirements of the written agreements. [B2.11.4.2]

- ❑ A copy of the HLA laboratory's current ASHI, EFI, CAP, or other appropriate accreditation certificate. Include documentation of certification for DNA-based typing. [B5.5]
  - ❑ For ASHI accreditation, include the accreditation letter in addition to the certificate.
  - ❑ For CAP accreditation, include the accreditation letter and the CAP Activity Menu.
  - ❑ If the laboratory is not accredited for stem cell transplantation (related and unrelated), submit documentation of HLA expertise available within the Cord Blood Bank for selecting the best matched donor for the recipient.

- ❑ Examples of completed labels used during all stages (in-process and at completion). Complete the labels as you would for use on a cord blood unit. The following labels must be provided for the following stages at a minimum and include the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum:
  [B6.6.2, B6.6.3, B6.6.4, B6.6.5, C7.6, D4.2.2, E4.5, E4.7, E5.4.7, and Appendices II and III]
  - ❑ After collection is complete. [B6.6.4, Appendix II]
  - ❑ Post - processing and prior to cryopreservation. [B6.6.4, Appendix II]
  - ❑ At distribution from the CBB to a clinical program. [B6.6.4, Appendix II]
  - ❑ Biohazard and warning labels and documentation of when they are used. [B6.6.3, Appendix II, Appendix III]
  - ❑ Partial label at distribution. [B6.6.5, Appendix II]
  - ❑ Label(s) used on outer containers for transport or shipping from collection. [C7.6 and Appendix II]

- ❑ Label(s) used on outer containers at distribution to a clinical program. [E5.4.7, and Appendix II]
- ❑ Documentation that accompanies a CB unit at distribution or an SOP that outlines accompanying documentation. [E4.7 and Appendix III]

❑ Current list of critical electronic record systems under the control of the CBB. Complete and upload the *Critical Electronic Record Systems* form or submit other documentation that contains the equivalent information for each critical record system. [B11.8.1]

❑ Documentation provided to the CB Collection Site(s) that outlines requirements for complying with CBB collection policies and Standard Operating Procedures. [C1.1]

❑ A description of the training process for CB unit collection personnel and how training is documented (e.g., forms, worksheets, other tools). [C2.4]

❑ For each of the validation studies below, submit:
- an approved validation plan,
- number of data points used,
- acceptance criteria,
- data collection,
- evaluation of data,
- summary of results,
- references, if applicable,
- documentation of review and approval of the plan, results, and conclusion:

- ❑ Collection procedure. [C6.3.4]
- ❑ Process for transport and shipping to maintain a designated temperature range in the immediate environment of the CB unit. [C7.5.2]
- ❑ Shipping container from collection to processing (only if continuous temperature monitoring is not used). [C7.5.3]
- ❑ Processing procedure. [D4.2.4]
- ❑ Cryopreservation procedure. [D4.2.4]

❑ Physical floor plan or diagram of the CB Processing Facility(ies). Label areas that are used for cord blood reception, processing, cryopreservation, storage, and data entry. [D1.2]

❑ Most recent completed stability assessment of cryopreserved CB units for post-thaw viability, potency, and container integrity. [D7.6]

❑ A description of the CB unit information sent to the Clinical Program at the time of selection for administration. [E3.4]

❑ 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: [E4.6]
- ❑ 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).

KEY PERSONNEL DOCUMENTATION

- ❑ Cord Blood Bank Director [B1.6 and Appendix I]:
  - ❑ Doctoral degree in medicine or in a related scientific field or a minimum of post-baccalaureate degree in a relevant science with a minimum of five (5) years of experience in the activities carried out in the CB Processing Facility If the Cord Blood Bank Director is a licensed physician, a medical license may serve as documentation.
  - ❑ Curriculum vitae (CV)

    OR
  - ❑ Summary of the Cord Blood Bank Director's:
    - Education
    - 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.
  - ❑ Documentation of at least ten (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 (at a minimum, 2 years). Complete and upload the *Educational Activities Form* 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 rounds).
    - Topic of activity (for example, hematology, cell transplantation).
    - Approximate number of hours of activity.

- ❑ Cord Blood Bank Medical Director [B1.6 and Appendix I]:
  - ❑ Current Medical License.
  - ❑ Curriculum vitae (CV)

    OR
  - ❑ Summary of the Cord Blood Bank Medical Director's:
    - Education
    - Training in hematopoietic cell transplantation, or blood or tissue banking.
  - ❑ Documentation of at least ten (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 (at a minimum, 2 years). Complete and upload the *Educational Activities Form* 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 rounds).
    - Topic of activity (for example, hematology, cell transplantation).
    - Approximate number of hours of activity.

- ❑ Cord Blood Collection Director [B1.6 and Appendix I]:
  - ❑ Curriculum vitae (CV)

    OR
  - ❑ Summary of the Cord Blood Collection Director's:
    - Education
    - Training and experience in hematopoietic cell transplantation, blood and tissue banking, or CB collection.
  - ❑ Documentation of at least ten (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 (at a minimum, 2 years). Complete and upload the *Educational Activities Form* 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 rounds)
    - Topic of activity (for example, hematology, cell transplantation).
    - Approximate number of hours of activity.

- ❑ Cord Blood Bank Processing Facility Director [B1.6 and Appendix I]:
  - ❑ Documentation of relevant doctoral degree.
  - ❑ Curriculum vitae (CV)

    OR
  - ❑ Summary of the Cord Blood Processing Facility Director's:
    - Education
    - Training and experience for the scope of activities carried out in the CB Processing Facility.
  - ❑ Documentation of at least ten (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 (at a minimum, 2 years). Complete and upload the *Educational Activities Form* 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 rounds).
    - Topic of activity (for example, hematology, cell transplantation).
    - Approximate number of hours of activity.

- ❑ Quality Unit Manager [B1.6 and Appendix I]:
  - ❑ Curriculum vitae (CV)

    OR
  - ❑ Summary of the Quality Unit Manager's training in quality management.
  - ❑ Documentation of at least ten (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 (at a minimum, 2 years). Complete and upload the *Educational Activities Form* 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 rounds).
    - 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 Standard Operating Procedures must be in English.

- ❑ A detailed list of all the CBB's and CB Collection Sites' controlled documents including identifier and title. [B3.2 and C3.2]

Specific policies and Standard Operating Procedures: 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, and selection. However, policies or Standard Operating Procedures explaining general Quality Management issues may be Level 1 or Level 2 documents.

- ❑ Establishment and maintenance of written agreements. [B2.4]
- ❑ Personnel requirements, training, competency assessment, and continuing education for each key position in the CBB. [B2.5]
- ❑ Change control, including required elements in B2.6.1-B2.6.7. [B2.6]
- ❑ Document management, including creation, assembly, approval, implementation, review, revision, storage, retention, archival, and retrieval of all controlled documents. [B2.7.2]
- ❑ The management and maintenance of records, including electronic records, if applicable. [B2.8]
- ❑ Actions to take in the event the CBB's operations are interrupted, including a continuity plan for critical functions. [B2.9]
- ❑ Maintaining confidentiality as required by these Standards. [B2.10]
- ❑ Performing internal and external audits and inspections of the CBB to verify compliance with elements of the Quality Management Program, operational policies and Standard Operating Procedures, these Standards, and Applicable Law. [B2.11]
- ❑ Occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). [B2.12]
- ❑ Qualification of critical services, manufacturers, vendors, equipment, software, supplies, reagents, and facilities. [B2.13]
- ❑ Validation of critical procedures of the CBB. [B2.14]
- ❑ Linkage of a CB unit including chain of identity, chain of custody, tracking from the infant donor to the recipient or final disposition, and tracing from the recipient or final disposition to the infant donor and mother. [B2.15]
- ❑ Evaluate details of clinical outcome data and CB unit characteristics. [B2.16]
- ❑ Transfer of inventory that meet the requirements of B10. [B2.17]
- ❑ Donor recruitment or registration and education. [B3.1.1 and C3.1.1]
- ❑ Maternal and infant donor screening and testing (including interpretation and acceptable results). [B3.1.2, C3.1.2]
- ❑ Informed consent. [B3.1.3 and C3.1.3]

- ❑ Suitability assessment of maternal and infant donors. [B3.1.4 and C3.1.4]
- ❑ Donor eligibility criteria and determination. [B3.1.5 and C3.1.5]
- ❑ Documentation of infant donor health at birth. [B3.1.7 and C3.1.7]
- ❑ Collection of CB units, associated samples, and maternal samples, including processes for both fixed and non-fixed collection sites as applicable. [B3.1.10 and C3.1.11]
- ❑ Transport and 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. [B3.1.13 and C3.1.14]
- ❑ Labeling of the CB unit and associated samples, forms, and maternal samples at the CB Collection Site (for both fixed and non-fixed collection sites), at the CB Processing Facility, and at release for administration. [B3.1.14, C3.1.16, and D3.1.13]
- ❑ Acceptance criteria for CB unit receipt (from both fixed and nonfixed collection sites, if applicable), processing, cryopreservation, and storage, including requirements for CB unit specifications. [B3.1.15, D3.1.3, D9.2, and Appendix V]
- ❑ Acceptable levels of hemodilution of maternal samples used for communicable disease testing. [B3.1.18, C3.1.18, and D3.1.14]
- ❑ Communicable disease testing, microbial cultures, hemoglobinopathy testing, and other testing. Acceptance criteria for test results must be defined. [B3.1.19 and D3.1.15]
- ❑ Criteria for release of CB units from quarantine, including nonconforming CB units. [B3.1.21 and D3.1.16]
- ❑ Criteria for qualification and listing of CB units for search and administration. [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 level of resolution, loci, timing, and verification of initial typing. [B3.1.25, D3.1.17, and E1.2.2.3]
- ❑ Collection and analysis of transplant outcome data. [B3.1.28]
- ❑ Standard Operating Procedure for obtaining informed consent or agreement to collect and bank a CB unit. [C4.1]
  - ❑ Unsigned examples of all informed consent forms or agreements. [C4.1]
- ❑ CB unit processing and cryopreservation. [D4.2.4]
- ❑ A copy of the written instructions to be followed if the storage device fails and evidence (e.g., picture) that written instructions to be followed if the storage device fails are displayed in the immediate area of the storage device and at each remote alarm location. [D8.4.6]

On-Site 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: [B11.8.7]
  - ❑ Systems development including the verification of calculations and algorithms [B11.8.7.1]
  - ❑ Numerical designation of system versions, if applicable [B11.8.7.2]
  - ❑ Prospective validation of system, including hardware, software, and databases [B11.8.7.3]
  - ❑ Installation of the system [B11.8.7.4]
  - ❑ Training and continuing competency of personnel in system use [B11.8.7.5]
  - ❑ Monitoring of data integrity [B11.8.7.6]
  - ❑ Back-up of the electronic records system on a regular schedule [B11.8.7.7]
  - ❑ System maintenance and operations [B11.8.7.8]