

FACT ACCREDITATION PROCESS REQUIREMENTS CHECKLIST Cord Blood Bank

This document provides guidelines for the FACT cord blood bank accreditation process. These guidelines pertain to banks applying for accreditation under the NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration.

ELIGIBILITY

- Review the current edition of the [Cord Blood Standards and Accreditation Manual](#).
- Determine eligibility requirements: [Cord Blood Bank eligibility requirements](#).
- Begin the process of applying for FACT accreditation by creating your bank's profile in the [Accreditation Portal](#) and the [FACT website](#). After your profile is approved, an email will be sent to the Bank Director that the Eligibility Application is available to complete.
- Complete and submit the Eligibility Application that describes your bank and accreditation goals.
- Submit a nonrefundable registration fee (initial applicants only). Contact FACT at 402-920-7001 or fact@factglobal.org for details about specific fee requirements.

COORDINATOR

Each bank is assigned a FACT Accreditation Coordinator to assist with questions or concerns you may have throughout the accreditation process.

- Your FACT Accreditation Coordinator will notify your bank's Director that the Compliance Application has been created. The Bank Director will need to review and approve the bank's accreditation goals and sites to be inspected. Once approved, the Compliance Application will be available to the bank's personnel.

COMPLETING THE COMPLIANCE APPLICATION

- Review the Compliance Application. Assign someone to complete each section. The [CB Self-Assessment Tool](#) contains all the Standards and questions in a compliance application and is a useful preparatory resource. FACT requires creation of a crosswalk between each standard and the supporting documents and records for the inspectors to reference on-site, promoting inspection efficiency. This crosswalk can be a helpful tool for preparing for accreditation and maintaining readiness throughout the accreditation cycle.
 - Identify the areas where no documentation exists.
 - Create new policies or Standard Operating Procedures (SOPs) and/or update existing policies or SOPs to document compliance.
- The Compliance Application in the accreditation portal requires document uploads for some standards. Required documents are listed in the [CB Document Submission Requirements](#).
- Within the Compliance Application there are select questions that include a required comment field (*Evidence or other comments*) to enter a description for how the program complies with the standard.
Example entry: Document Control SOP, section 6.1, page 4, refer to highlighted section.

- To assist with tracking which questions need additional evidence, flag questions in the Compliance Application. You may keep questions flagged until all required information is entered.
- The Compliance Application cannot be submitted until all questions are answered, all required documents are uploaded, all flags are removed, and the application is signed by the Cord Blood Bank Director and Facility Directors.
- The submitted Compliance Application will be reviewed by your assigned Accreditation Coordinator. Requests for information (RFIs) are generated when additional information or documents are required.
- A Bank applying for accreditation for the first time is given 12 months after approval of the Eligibility Application to prepare documentation, adjust processes to comply with the NetCord - FACT Standards, and submit the Compliance Application. A Bank renewing accreditation is expected to submit the Compliance Application 11 months prior to accreditation expiration. Timely responses are critical to achieving and maintaining FACT accreditation.

Note: Inspections are conducted under the current edition of Standards; this may require completion of a new application if a new set of Standards becomes active prior to completion of the Compliance Application.

BEFORE THE ON-SITE INSPECTION

- After the FACT Accreditation Coordinator determines the Compliance Application is complete, you will be contacted by FACT for potential inspection dates. Provide FACT several sets of consecutive dates for the two-day inspection. Dates must be at least eight weeks in the future. Additional inspection day(s) may be required if there are multiple collection sites, multiple processing sites, off-site storage sites, and/or marketing sites, or if travel time between sites is lengthy.
 - Provide only dates when **all** key PERSONNEL will be available at **each site**. At a minimum, this includes the CBB Director, CBB Medical Director, CB Collection Director(s), the CB Processing Facility Director, and the Quality Unit Manager.
 - Submit dates that are acceptable for all SITES (e.g., bank, collection sites, processing facilities, off-site storage facilities). Keep submitted date(s) available until confirmation of the selected date(s). The inspectors **MUST** visit each site chosen for inspection and meet with key personnel. This may require clearance from an administrator (e.g., Director of Nursing).
 - Your bank will be notified of the inspection team.

Note: If there are objections to any member of the inspection team, your bank must notify FACT within five business days of receiving notices of the proposed inspection team.
 - After an inspection date(s) is selected, notify ALL KEY PERSONNEL and SITES and instruct them to remain available. In addition, identify designated personnel who must be available throughout the day to accompany each of the inspectors and assist as needed.
- For inspections in which the documents are not in English, the bank must arrange to have a translator accompany EACH inspector during the entire inspection.
- If inspector travel costs exceed historical averages, your bank may be assessed a travel surcharge.
- Provide FACT with the name and address of a convenient, reasonably priced, and safe hotel.

- The Bank Director or designee should communicate the following information to the Inspection Team Leader:
 - Arrangements to pick up the inspectors at their hotel. If this is not possible, provide directions to the bank, options for transportation, and the estimated time that will be required to reach your bank.
 - Inform the team of where you want to meet upon arrival at your bank or sites not located at the bank.
- Reserve a room for the entire inspection for the inspectors where they can review records, Standard Operating Procedures, and documents. In addition, for the initial meeting and the exit interview, reserve a room that is adequate in size to accommodate the entire inspection team and key personnel.
- Arrange to provide a modest business lunch for the inspection team on each day of the inspection, including inspectors not on-site. Most teams will use the lunch hour as a working lunch.
- Ensure inspectors have continuous internet access throughout the inspection.
- The Inspection Team Leader creates an agenda for the on-site inspection and coordinates with the bank. If you do not have a detailed agenda one week before the on-site inspection, the Cord Blood Bank Director should contact the Inspection Team Leader and/or the FACT Accreditation Coordinator to obtain the agenda. The Bank Director is responsible for disseminating the inspection agenda to all key personnel within the bank.
 - The Bank Director may contact the Team Leader at any time to discuss the agenda or specifics of the inspection.

PREPARING ON-SITE DOCUMENTATION

- Compile documents and records that support compliance for each FACT standard.
- Organize and label the documents and records by standard.
- FACT requires creation of a crosswalk between each standard and the supporting documents and records for the inspectors to reference on-site. This will promote inspection efficiency.
 - The [CB Self-Assessment Tool](#) may be useful for documenting the crosswalk.
- The Compliance Application can be exported to Excel and used as a crosswalk, including information entered in the field labeled: *"Evidence or other comments."*

The following documents should be immediately available for the inspectors to review:

- Quality management documents, including meeting minutes, audits, adverse reaction reports, occurrence reports, and corrective and preventive actions and effectiveness of the actions.
- SOPs and work instructions for collection, processing, banking, and release.
- Documentation of bank and contracted staff training and continued competency, including current licenses, contracts, and other documents that have expired between time of submission and the inspection date.
- Documentation of proficiency testing.
- Documentation demonstrating quality improvement and assessment including audits, corrective actions, validations, qualifications, occurrence reports, and adverse event records.
- IRB approval documentation, if applicable.

- Validation of electronic record systems if the system is within the control of the facility requesting accreditation and is considered a critical electronic record system.

DURING THE ON-SITE INSPECTION

- The introductory meeting should include all key personnel of the cord blood bank and members of the inspection team.
 - Introduction of cord blood bank personnel and inspection team members.
 - The Bank Director presents information to the inspection team about the bank that may be helpful, especially information that was not required in the Compliance Application. It is helpful to review the structure of the bank and the location of the sites, particularly if these issues are complex and/or there are off-site locations. Slide presentations are helpful, but not required. This presentation should not exceed 10-15 minutes.
- A knowledgeable person must be available for each inspector at all times to answer questions, find documents or Standard Operating Procedures (SOPs), assist with record navigation, etc. Appropriate individuals include a quality unit manager, collection site nurse supervisor, or processing facility supervisor.
- For inspections in which the documents are not in English, the bank must provide a translator to accompany EACH inspector during the entire inspection.
- Be prepared to have someone escort the inspectors to each of the sites. If there are distant sites, be prepared to transport the inspectors and accompany them at those sites.
- Inspectors will meet with key personnel at each of the sites. Ensure those key personnel are available during the scheduled time of the visit for each of the sites.
- Be prepared to gather additional documentation expeditiously, as requested by the inspection team to allow sufficient time for review, before the inspection concludes.
- Be prepared to demonstrate a procedure. If none is scheduled, inspectors will request a mock procedure be performed relevant to the area being inspected.
- Assume that the inspectors will want a closed session during the lunch hour but may wish to use a portion of this time to communicate with your personnel. Be available to address questions or concerns related to completing the inspection with the inspection team before your lunch break.
- At the end of the inspection, the inspectors may wish to meet privately with the Bank Director and/or designated directors if there are issues that may be sensitive or confidential. Be available for this meeting.
- The purpose of the Exit Interview is for the inspectors to summarize their major findings and to outline the remainder of the accreditation process. Not all citations are discussed at the Exit Interview. Remember, the FACT Accreditation Coordinators and the Accreditation Committee review citations. The FACT Board of Directors will determine the final decision on accreditation status. The inspectors have specifically been instructed not to speculate on the accreditation outcome.

AFTER THE ON-SITE INSPECTION

- Additional documentation cannot be submitted after the on-site inspection until the Accreditation Committee reviews your bank's application and a request for information is initiated in the Accreditation Portal.

- Do not make any changes to your cord blood bank or processes based on the inspection until you have received the final Accreditation Report.
- The inspection team will submit an inspection report to FACT after the on-site inspection.
- The Accreditation Coordinator reviews the inspection report and prepares the Accreditation Report for the FACT Cord Blood Accreditation Committee.
- The FACT Cord Blood Accreditation Committee reviews the Accreditation Report and makes a determination regarding the outcome. Significant questions, problems, and controversial or precedent-setting issues will be referred to the FACT Board of Directors for resolution.
- The Bank Director and designated personnel will be notified by email after an Accreditation Committee decision is achieved. Refer to the [Timelines for Organization Accreditation and Renewal](#) for these processes, and contact your FACT Accreditation Coordinator if you have questions or need information.
- Your bank will receive the accreditation decision and the Accreditation Report, which includes all citations, variances, suggestions, and required responses. Refer to the [FACT Applicant Response Template](#) for response examples.
- All citations must be adequately addressed prior to accreditation. Responses are reviewed by the FACT Accreditation Coordinator, the Chief Medical Officer, and if necessary, the FACT Cord Blood Accreditation Committee. An accreditation recommendation is submitted to the FACT Board of Directors for final determination.
- If you have questions regarding a citation, request clarification from your FACT Accreditation Coordinator.
- After the accreditation has been awarded, the Bank Director will receive a FACT accreditation certificate and the bank will be included on the [FACT list of accredited organizations available on the FACT website](#).
- Please complete an [evaluation](#) regarding the accreditation and inspection process. Your comments, suggestions, and observations are important for continued improvement in the FACT's processes.