

FACT APPLICANT GUIDELINES Information for Cord Blood Bank Applicants

COMPLETING THE COMPLIANCE APPLICATION

- Complete the current [CB Self-Assessment Tool](#).
- Review the Compliance Application. Assign someone to complete each section.
 - Generate missing procedures or work/job instructions.
 - Address the areas where you cannot document that you meet the Standard. Ensure that any new protocols or procedures are written or existing protocols/ procedures are revised to document compliance.
- The Compliance Application requires document uploads for some standards. Upload the required documents when requested. The [CB Document Submission Requirements](#) includes the list of documents that must be submitted.
- For each standard in the Compliance Application, a feature that allows you to mark the standard as “Not Complete” is available to assist you with tracking which standards need additional evidence entered. You may keep the standard marked until all required information has been entered.
- The Compliance Application cannot be submitted unless all questions have been answered, all required documents are uploaded, and the application has been signed by the Cord Blood Bank and Facility Directors.
- Requests for information (RFIs) are generated by the FACT Accreditation Coordinator or inspectors when additional information or documents are required.
- Banks applying for accreditation for the first time are given 12 months after submitting their online Eligibility Application to arrange their documentation, adjust processes to be in compliance with the FACT Standards, and submit their Compliance Application. Banks in the process of renewal accreditation must submit their Compliance Application at least nine months prior to accreditation expiration. Timely responses are critical to achieve FACT accreditation.

BEFORE THE ON-SITE INSPECTION

- When the Compliance Application is considered complete by FACT staff, you will be contacted for potential inspection dates. Please be prepared to give several sets of consecutive dates for the two-day inspection. Dates must be at least six weeks in the future. If more than four collection sites are to be inspected and/or if there is a long travel time between collection sites, an additional day may be required for the collection site inspection.
 - Schedule the on-site inspection for dates when ALL KEY PERSONNEL are available. At a minimum, this includes the CBB Director, CBB Medical Director, CB Collection Director(s), the CB Processing Facility Director, and the Quality Manager. In addition, there must be designated personnel available throughout the day to accompany each of the inspectors, assist as needed, and act as a translator for the inspector if required.
 - Schedule the on-site inspection on days that are acceptable for all sites (e.g., bank, collection sites, processing facilities, off-site storage facilities). The inspectors MUST visit each site chosen for inspection and talk with key personnel at these sites. This may require clearance from an administrator, Director of Nursing, etc.
- If inspector travel costs exceed historical averages, your program may be assessed a travel surcharge.
- Provide the FACT Accreditation Office with the name of a convenient, reasonably priced, and safe hotel.
- The Bank Director or designee should communicate the following information to the Inspection Team Leader:
 - Provide inspectors with directions to the facility. It is acceptable to arrange to pick up the inspectors at their hotel. If this is not possible, provide them information about available transportation and estimate the time required to reach your facility.
 - Inform the inspection team of where you want them to meet you upon arrival at your facility.
- For the days of the inspection, reserve a room for the inspectors where they can review procedure manuals 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, key personnel, and others the applicant wishes to invite.
- Arrange to provide a modest lunch for the inspection team on each day of the inspection. Most teams utilize the lunch hour, at least in part, as a working lunch.
- Arrange for a computer(s) with internet access that inspectors can use throughout the inspection, or, at a minimum, during the lunch hour. Notify the inspection team of the computer arrangements that have been made prior to the inspection.
- The Inspection Team Leader will provide a schedule for the on-site inspection. If you do not have a detailed schedule one week before the on-site inspection, the Cord Blood Bank Director should contact the Inspection Team Leader and/or the FACT Office to obtain it. The Bank Director is responsible for disseminating the inspection agenda to all key personnel within the program.

- Review the inspection agenda provided by the Team Leader.
- The Bank Director may contact the Team Leader at any time to discuss the schedule or specifics of the inspection.

DURING THE ON-SITE INSPECTION

- The initial interview should include all key personnel of the cord blood bank and members of the inspection team.
- The Bank Director should plan to introduce the members of the applicant cord blood bank to the inspectors, and present information to the inspection team about the bank that may be helpful (especially information that was not required on the Compliance Application). It is helpful to review the structure of the bank and the location of the applicant sites, particularly if these issues are complex and/or there are any off-site locations. This presentation should not exceed 10 to 15 minutes.
- Knowledgeable personnel must be available to the inspectors at all times to answer questions, find documents or procedures, provide translation services, etc. Appropriate individuals would be a quality manager, collection site nurse supervisor, or processing facility supervisor.
- Inspectors need to talk to key personnel at each of the sites. Be certain that they are available during the scheduled time of the visit for each of the sites.
- The following documents should be immediately available for the inspectors to review:
 - Quality assessment and improvement documents, including any internal audits performed by the bank.
 - Procedures or work/job instructions for collection, processing, banking, and release.
 - Documentation of physician and staff training and continued competency, including documentation of current license, contracts, and other documents that have expired between time of submission and the inspection date.
 - Validation studies of key processes.
- Be prepared to gather additional documentation requested by the team during the time that they are present at your site. At the discretion of the inspector, the bank may upload specified documents that are reviewed on site by the inspector into the Compliance Application.
- Assume that the inspectors want some closed-session time during the lunch hour, but they may also wish to use a portion of this time to communicate with the applicant. Be available. Be sure to check with the inspection team for questions or concerns related to completing the inspection visit before you leave for your own 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 to be raised that may be of a sensitive or confidential nature. Be available for this meeting.

- ❑ The purpose of the Exit Interview is to allow 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 that the citations are reviewed by the FACT Accreditation Coordinators and the Accreditation Committee, and the final decision on accreditation status is determined by the Board of Directors. The inspectors have specifically been instructed not to speculate on the accreditation status your program will attain after Accreditation Committee review.
- ❑ The Bank Director and other individuals listed as alternate contacts on your Compliance Application are notified by email when an Accreditation Committee decision has been reached. Consult the timeline for these processes, and feel free to contact the FACT Accreditation Office if you have questions or need information.
- ❑ Additional documentation cannot be submitted until the Accreditation Committee has reviewed your accreditation report and a request for information has been initiated by the FACT Accreditation Coordinator in the Accreditation Portal.

AFTER THE ON-SITE INSPECTION

- ❑ Your cord blood bank receives notice of the Accreditation Committee's decision and directions for responding to citations via an accreditation report.. Do not make any changes to your cord blood bank until you have received the accreditation report.
- ❑ All citations must be adequately addressed prior to accreditation; some citations contain multiple items that need to be corrected.
- ❑ If you have any questions regarding a citation, request clarification from your FACT Accreditation Coordinator.
- ❑ Please complete an [evaluation](#) regarding the inspection process. Each individual participating in the inspection process may complete an evaluation. Your comments, suggestions, and observations are important for continued improvement in the inspection and accreditation processes.