FACT ACCREDITATION PROCESS REQUIREMENTS CHECKLIST

Cellular Therapy

This document provides guidelines for the FACT cellular therapy accreditation process. These guidelines apply to organizations applying for accreditation under the FACT-JACIE Standards for Hematopoietic Cellular Therapy, the FACT Standards for Immune Effector Cells, and the FACT Common Standards for Cellular Therapies.

COMPLETING THE COMPLIANCE APPLICATION

- Review the applicable Self-Assessment Tool for the relevant set of Standards. Assign someone to complete each section. Refer to references below to access the appropriate document.
  - Identify the areas where no documentation exists.
  - Create new policies or Standard Operating Procedures (SOPs) or update existing policies/Standard Operating Procedures to document compliance.

- The Compliance Application in the accreditation portal requires document uploads for some standards. Required documents for each set of Standards are listed in the relevant Document Submissions Requirements form. Refer to the references below to access the appropriate document.

- 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 unless all questions are answered, all required documents are uploaded, all flags are removed, and the application is signed by the Program Director (or Facility Director for facilities applying independently of a Clinical Program) and applicable Facility Directors.

- Requests for information (RFIs) are generated by your assigned FACT Accreditation Coordinator when additional information or documents are required.

- Organizations applying for accreditation for the first time are given 12 months after approval of their Eligibility Applications to prepare their documentation, adjust processes to comply with the FACT Standards, and submit their Compliance Applications. Organizations in the process of renewal accreditation must submit their Compliance Applications 11 months prior to accreditation expiration. Timely responses are critical to achieving/maintaining FACT accreditation.
BEFORE THE ON-SITE INSPECTION

- When the FACT Accreditation Coordinator considers the Compliance Application complete, you will be contacted for potential inspection dates. Provide the FACT office several options.

- Send only dates when all key PERSONNEL will be available for the inspection at each site. At a minimum, this includes the Program Director, the Collection Facility Director and Medical Director, and the Processing Facility Director and Medical Director.

- Send only dates that are acceptable for all SITES (e.g., hospitals, off-site storage facilities). The inspectors MUST visit each site and meet with key personnel. This may require clearance from an administrator (e.g., Director of Nursing).

- When a date is selected, notify ALL KEY PERSONNEL and SITES and instruct them to remain available. In addition, identify designated personnel who will be available throughout the day to accompany each of the inspectors and assist as needed, including one person familiar with charts and data who will be available to assist with chart and data management review.

- For inspections in which the documents are not in English, the organization must provide a translator for EACH inspector during the inspection.

- If inspector travel costs exceed historical averages, your organization may be assessed a travel surcharge.

- Provide the FACT Office with the name of a convenient, moderately priced hotel.

- The Program Director or designee should communicate the following information to the Team Leader:
  - Arrangements to pick up the inspection team at their hotel. If this is not possible, provide directions to the facility, options for transportation, and the estimated time that will be required to reach your facility.
  - Inform the team of where you want to meet upon arrival at your facility.

- Reserve a room for the entire day for the inspectors where they can review charts, 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 and key personnel.

- Arrange to provide a modest business lunch for the inspection team. Most teams will use the lunch hour as a working lunch.

- Arrange for a computer(s) with internet access that inspectors can use throughout the inspection day.
PREPARING ON-SITE DOCUMENTATION

- Compile documents and medical records that support compliance for each FACT standard.
- Organize and label the documents and records by standard.
- Create a crosswalk between each standard and the document(s) and record(s) that support that standard for the inspector to reference onsite. The self-assessment tool may be useful for documenting the crosswalk. This will promote inspection efficiency. Refer to the references below to access the appropriate document.

The following documents should be immediately available for the inspectors to review:
- Quality management documents.
- SOPs for the clinical, collection, and processing areas.
- Clinical outcomes requirements as requested by the Clinical Outcomes Committee, as applicable.
- Data audit requirements as requested by the FACT-CIBMTR Data Audit Committee, as applicable.
- Documentation of physician and staff training and continued competency, including documentation of current license(s), contracts, and other documents that have expired between time of submission and the inspection date.
- Documentation of proficiency testing.
- Documents 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.

Review the FACT website for additional information regarding preparation for the inspection day. Though not required, two specific webinars are suggested: Quality Organization Virtual Roundtable and Organizational Self-Assessments.

DURING THE ON-SITE INSPECTION

- The initial interview should include all key personnel of the cellular therapy program and members of the inspection team.
- The Program Director introduces the members of the cellular therapy program to the inspectors, and presents information to the inspection team about the program that may be helpful, especially information that was not required in the Compliance Application. It is helpful to review the structure of the organization and the location of the sites to be inspected, 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 chart navigation, etc. Appropriate individuals include a quality manager, data manager, collection center nurse supervisor, and laboratory supervisor.
- For inspections in which the documents are not in English, the organization must provide a translator for EACH inspector during the inspection.
The Inspection Team Leader will provide an agenda for the on-site inspection. If you do not have a detailed schedule one week before the on-site inspection, the Program Director should contact the Team Leader and/or the FACT Accreditation Coordinator. The Program Director is responsible for disseminating the inspection agenda to all key personnel within the program. The Program Director may contact the Team Leader at any time to discuss the agenda or specifics of the 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 there 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.

- 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 Program 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 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 organization’s application and a request for information is initiated in the Accreditation Portal.

- The Program Director and designated personnel are notified by email when an Accreditation Committee decision is achieved. Refer to the timeline for these processes, and contact your FACT Accreditation Coordinator if you have questions or need information.

- Your program will receive a final inspection summary including the accreditation decision. All citations must be adequately addressed prior to accreditation.

- Do not make any changes to your organization or processes until you have received the final inspection summary.

- If you have questions regarding a citation, request clarification from your FACT Accreditation Coordinator.

- Please complete an inspection evaluation regarding the inspection process. Your comments, suggestions, and observations are important for continued improvement in the inspection and accreditation processes.
REFERENCES

Hematopoietic Cellular Therapy

1. Hematopoietic Cellular Therapy Self-Assessment Tool, Seventh Edition

Immune Effector Cells


Common Standards