**FACT ACCREDITATION PROCESS REQUIREMENTS CHECKLIST
Cellular Therapy**

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

The applicable Standards, Accreditation Manual, self-assessment tool, grids, and other forms you will need during the application process are located on the applicable Standards webpage:

* [Hematopoietic Cell Therapy Standards](https://www.factglobal.org/standards/hct-standards/): <https://www.factglobal.org/standards/hct-standards/>
* [Immune Effector Cell Standards](https://www.factglobal.org/standards/immune-effector-standards): <https://www.factglobal.org/standards/immune-effector-standards>
* [Common Standards](https://www.factglobal.org/standards/common-standards): <https://www.factglobal.org/standards/common-standards>

FACT policies and Standard Operating Procedures, including *Accreditation Process Policy*, *Maintaining Accreditation Policy*, and *Timelines for Organization Accreditation and Renewal*, can be accessed on the following webpage: <https://www.factglobal.org/education-and-resources/general/fact-policies-and-standard-operating-procedures/>.

**ELIGIBILITY APPLICATION**

[ ]  **Review the Standards:** Review the current edition of the applicable [Cellular Therapy Standards and Accreditation Manual](https://www.factglobal.org/standards/).

[ ]  **Confirm Eligibility:** Determine if your cellular therapy organization meets the eligibility requirements: [Cellular Therapy Program Eligibility Requirements](https://www.factglobal.org/accreditation-process/ct-accreditation-eligibility/).

[ ]  **Request Eligibility Application:** Request an Eligibility Application by creating your organization profile in the portal at: <https://portal.factglobal.org/RequestAccess> and the [FACT website](https://www.factglobal.org/). The Manager of Accreditation Services will create the Eligibility Application and email instructions to access the Eligibility Application.

[ ]  **Submit Eligibility Application:** Complete and submit the Eligibility Application, providing details about your organization and accreditation goals.

[ ]  **Submit Business Associate Agreement:** Submit a signed Business Associate Agreement (BAA). A countersigned copy will be returned. If needed, contact FACT at 402-920-7001 or fact@factglobal.org for assistance.

[ ]  **Pay Registration Fee:** Submit a nonrefundable registration fee (for initial applicants only). Contact FACT at 402-920-7001 or fact@factglobal.org for details about specific fee requirements.

**COMPLETING THE COMPLIANCE APPLICATION**

[ ]  **Accreditation Coordinator Assignment:** A FACT Accreditation Coordinator is assigned to each organization to assist with any questions during the accreditation process.

[ ]  **Approve Compliance Application:** The FACT Accreditation Coordinator will notify the Organization Director to review and approve the Compliance Application, including the accreditation goals and sites that will be inspected. After approval by the Director, organization personnel receive an email notification that the Compliance Application, consisting of customized checklists for each site to be inspected, is available to document compliance with each Standard.

[ ]  **Review and Assign Tasks:** Review the Compliance Application and assign someone to complete each section. It may be helpful to use the Self-Assessment Tool, which contains all Standards and questions, to prepare for completion of the Compliance Application.

[ ]  **Create a Crosswalk:** Create a crosswalk between each Standard and supporting documents within your organization for inspectors to reference on-site.

[ ]  **Identify Missing Documentation:** Determine where documentation is lacking.

[ ]  **Create or Update Policies:** Create new policies or Standard Operating Procedures (SOPs) and update existing ones to document compliance.

[ ]  **Upload Documents:** Some standards require documents to be submitted with the Compliance Application in the accreditation portal. For a complete list of required documents, refer to the Document Submission Requirements for each set of [Standards](https://www.factglobal.org/standards/).

[ ]  **Submit Completed Application:** Ensure that all questions have been answered, that all required documents have been uploaded, and that the application has been signed by the Organization Director and applicable Facility Directors.

[ ]  **Coordinator Review:** The Accreditation Coordinator will review the completed Compliance Application; requests for Information (RFIs) will be entered if further information is needed.

[ ]  **Adhere to Deadlines:** Refer to the [*Timelines for Organization Accreditation and Renewal*](https://www.factglobal.org/education-and-resources/general/fact-policies-and-standard-operating-procedures/).

* **Initial applicants:** Submit the completed Compliance Application and all required documents within 12 months of the Eligibility Application approval.
* **Renewal applicants:** Submit the Compliance Application and all required documents 11 months prior to accreditation expiration.

**Note:** Inspections are conducted using the current edition of Standards. A new application may be required if a new set of Standards becomes effective prior to completion and submission of your Compliance Application.

**SCHEDULING THE ON-SITE INSPECTION**

[ ]  **Schedule Inspection**: The Business Manager will contact your organization to schedule the on-site inspection dates. Please submit several potential inspection dates that meet the criteria below and are at least eight weeks in advance.

* **Ensure Key Personnel Availability:** For each potential inspection date submitted, confirm the availability of all key personnel for each site, including the Organization Director, the Clinical Program Director, the Collection Facility Director and Medical Director, the Processing Facility Director and Medical Director, and the Quality Managers.
* **Confirm Site Availability:** For each potential inspection date submitted, confirm all sites (e.g., inpatient and outpatient sites, collection sites, processing sites, off-site storage facilities) are available.
* **Inspection Team Notification:** The Business Manager will identify an appropriate inspection team and will notify the Organization Director. If there are objections or a perceived conflict of interest regarding the assigned inspection team, notify FACT within five business days.
* **Inform Key Personnel:** When the inspection date and team is confirmed, inform all key personnel to ensure they are available. Designate personnel to accompany each inspector and assist as needed, including someone familiar with accessing electronic medical records.

[ ]  **Arrange for Translators:** If documents are not in English, arrange for a translator to accompany each inspector throughout the inspection.

[ ]  **Provide Hotel Information:** Provide to FACT the name and address of a convenient, reasonably priced, and safe hotel.

[ ]  **Reserve Inspection Room(s):** Reserve a suitable workroom for the inspection that allows for chart and document review. In addition, identify a room for the Initial Introductory Meeting and the Exit Interview that is spacious enough to accommodate key personnel.

[ ]  **Arrange Lunch:** Plan a modest business lunch for the inspection team, including inspectors not on-site. Arrange a private room for the inspection team to permit a working lunch.

[ ]  **Ensure Internet Access:** Provide continuous Internet access to the inspectors throughout the inspection.

[ ]  **Coordinate with Inspection Team Leader:**

* **Arrange Transportation:** Coordinate transportation for inspectors from their hotel or provide clear directions if they are traveling on their own.
* **Designate Meeting Location:** Specify a meeting location at the organization to meet the inspection team.

[ ]  **Inspection Agenda:** Ensure the Organization Director has received the inspection agenda from the Team Leader at least one week before the inspection and has communicated the agenda to key personnel. The Organization Director may contact the Team Leader or Accreditation Coordinator to discuss the agenda or inspection specifics at any time.

**PREPARING ON-SITE DOCUMENTATION**

[ ]  **Create a Crosswalk:** FACT requires creation of a crosswalk between each standard and the supporting documents, improving inspection efficiency.

* The applicable [Standard Self-Assessment Tool](https://www.factglobal.org/standards) may be useful for documenting the crosswalk.
* The Compliance Application can be exported to Excel and used as a crosswalk. Information entered in the comment fields is included in the exported Excel file.

[ ]  **Compile Supporting Documents:** Gather all documents and records that demonstrate compliance with each FACT standard. Label and organize the documents and records according to the corresponding standard.

[ ]  **Documents for Immediate Review:** Ensure all required documents are readily available for inspector review including:

* Quality management documents, including meeting minutes, audits, adverse reaction reports, occurrence reports, corrective and preventive actions, and evidence of effectiveness of the quality management program.
* Applicable SOPs.
* Recipient and donor records and collection and processing records, including examples of occurrence management (e.g., ineligible donors, products with positive microbial culture results, adverse reactions).
* Staff training and competency records.
* Agreements; proficiency testing records.
* Validation and qualification studies.
* Applicable IRB approval documentation.
* Additional documentation requested by the Clinical Outcomes Improvement Committee or the Data Audit Committee, as applicable.
* Specific documents requested by the inspection team.

**DURING THE ON-SITE INSPECTION**

[ ]  **Introductory Meeting:** Conduct an Introductory Meeting with all key personnel and the inspection team.

* **Introduce Personnel:** The Organization Director will introduce the cellular therapy program personnel.
* **Inspection Team:** The inspection team members will introduce themselves and identify their areas of inspection responsibility.
* **Presentation:** The organization personnel will provide a 10-15 minute overview of the organization, highlighting important information. Include the organization structure and the location of the sites, especially if complex. A slide presentation is helpful but not required. If used, provide a copy of the presentation to the inspection team.

[ ]  **Provide Inspector Support:** Ensure a knowledgeable person, such as a quality manager, data manager, collection center nurse supervisor, or processing facility supervisor, is available for each inspector at all times to assist with questions, document retrieval, SOP navigation, and record review.

* **Translators:** For inspections where documents are not in English, provide a translator for each inspector.
* **Escort Inspectors:** Designate personnel to escort inspectors to each site. Arrange transportation to all sites.
* **Personnel Interviews:** Ensure personnel are available to meet with inspectors during the scheduled time.

[ ]  **Demonstrations:**

* **Procedures:** Each inspector is expected to observe a relevant procedure. Demonstrate the requested procedure or perform a mock procedure relevant to the inspected area.
* **Tracking and Tracing:** Demonstrate tracking and tracing of products and processes from donor identification through product collection, processing, storage, and administration.

[ ]  **Provide Lunch:** Inspectors will have a closed working session during lunch. Be available to address any questions or concerns.

[ ]  **Private Meeting, if needed:** Inspectors may request a private meeting with the Organization Director or other directors prior to the Exit Interview to discuss sensitive or confidential issues. Ensure availability for this meeting.

[ ]  **Exit Interview:** The inspectors will summarize their major findings and explain the next steps in the accreditation process. Not all citations will be discussed at this time. Final accreditation decisions will be made by the FACT Cellular Therapy Accreditation Committee with approval by the FACT Board of Directors. Inspectors will not speculate on the accreditation outcome.

**AFTER THE ON-SITE INSPECTION**

[ ]  **Inspection Report Submission:** The inspection team will submit an inspection report to FACT after the on-site inspection.

[ ]  **Report Review and Preparation:** The Accreditation Coordinator will review the inspection report and present it to the FACT Cellular Therapy Accreditation Committee.

[ ]  **Committee Decision:** The FACT Cellular Therapy Accreditation Committee will review the Accreditation Report and determine the outcome. Significant questions, issues, or precedent-setting concerns will be referred to the Board of Directors for resolution.

[ ]  **Receive Accreditation Report:** The Accreditation Report, including any citations, variances, suggestions, and required responses, is sent to the organization. Address citations according to the [*FACT Applicant Response Template*](https://www.factglobal.org/standards/hct-standards/). Direct any questions to your assigned Accreditation Coordinator.

[ ]  **Address Citations:** All citations must be adequately addressed before accreditation is awarded. Responses to citations are reviewed by the FACT Accreditation Coordinator, the Chief Medical Officer, and if needed, by the FACT Cellular Therapy Accreditation Committee.

[ ]  **Accreditation Awarded**: After all deficiencies have been corrected satisfactorily, accreditation is awarded. The Organization Director will receive a FACT accreditation certificate and the organization will be included on the [public list of accredited organizations on the FACT website.](https://accredited.factglobal.org/)

[ ]  **Submit an Evaluation:** Complete the accreditation and inspection process [evaluation](https://redcap.factglobal.org/surveys/?s=MN4TRYDFXKDHK43Y). Feedback is essential to help FACT improve its processes.

**MAINTAINING ACCREDITATION**

[ ]  **Maintain Compliance:** Continuously meet or exceed all current Standards. Review the current edition of the applicable [Cellular Therapy Standards and Accreditation Manual](https://www.factglobal.org/standards/) to ensure ongoing compliance.

* + **New Edition of Standards:** If a new edition is published, perform a self-assessment to identify and implement all necessary changes to maintain full compliance.

[ ]  **Report Changes Promptly**: Notify FACT within 90 days of any significant changes, including relocations, service expansions or cessations, organization name changes, Director changes, ownership changes, mergers, or any changes required by governmental regulations.

[ ]  **Submit Annual Report**: Submit the Annual Report one year after accreditation to document continued compliance with Standards. Complete the report and submit any additional documentation requested by the Accreditation Committee.

[ ]  **Submit Renewal Report:** Submit the Renewal Report 14 months prior to accreditation expiration. This report documents your organization’s activities, personnel, facilities, and accreditation goals to support continued accreditation. The information will be used to create your renewal Compliance Application.