

 <p>FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY</p> <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: ACC.6.1.003 Revision: 8 Approval Date: 03/September/2023 Page 1 of 8 Effective Date: 03/September/2023</p>
<p>Maintaining Accreditation Policy</p>		

1.0 Purpose

The purpose of this document is to describe the policy used for ensuring organizations accredited by FACT maintain compliance with applicable standards and accreditation requirements during an accreditation cycle.

2.0 Scope

This policy applies to organizations accredited by FACT.

3.0 Responsibility

- 3.1 It is the responsibility of FACT staff and the FACT Cellular Therapy and Cord Blood Accreditation Committees (“FACT Accreditation Committee”) to ensure this policy is followed.
- 3.2 It is the responsibility of the accredited organization to ensure all requirements for continued FACT accreditation are met during accreditation cycles.

4.0 References

- 4.1 [Accreditation Process Policy](#), ACC.6.1.001
- 4.2 [Clinical Outcomes Corrective Action Plan Policy](#), ACC.6.1.007
- 4.3 [Data Audit Policy](#), ACC.6.1.006
- 4.4 [Hearsay Evidence](#), LGL.4.1.001
- 4.5 [Reviewing Complaints and Grievances](#), LGL.4.6.001
- 4.6 Standards
 - 4.6.1 FACT Common Standards for Cellular Therapies
 - 4.6.2 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration
 - 4.6.3 FACT Standards for Immune Effector Cells
 - 4.6.4 NetCord - FACT International Standards for Cord Blood Collection, Banking, and Release for Administration
- 4.7 [Suspension or Termination of Accreditation](#), ACC.6.1.005

4.8 [Timelines for Organization Accreditation and Renewal](#), ACC.6.1.008

5.0 Definitions and Abbreviations

- 5.1 Add-On Inspection: An interim inspection required for the expansion of service(s).
- 5.2 Annual Accreditation Fee: Annual fee set forth according to the current fee structure available at www.factglobal.org.
- 5.3 Facility: A location where activities covered by the accreditation process and applicable standards are performed.
- 5.4 FACT Accreditation Committee: Refers to either the cord blood bank or cellular therapy program accreditation committee as described in this policy.
- 5.5 Interim Inspection: An inspection of an accredited organization occurring outside the routine accreditation cycle.
- 5.6 Organization: Clinical program, cellular therapy collection facility, cellular therapy processing facility, cord blood bank (including cord blood collection sites and cord blood processing facilities), facility under the Common Standards, or immune effector cellular therapy program, that has achieved or is applying for FACT accreditation.
- 5.7 Suspension of Accreditation: Temporary discontinuation of accreditation. Accredited organization will be removed from the list of accredited organizations on the FACT website pending resolution of issue. Upon resolution of issue, accreditation will be reinstated without a change in expiration date.
- 5.8 Termination of Accreditation: Organization's accreditation is revoked, and a reapplication and completion of the accreditation process will be required to regain accreditation.

6.0 Maintaining Accreditation

- 6.1 Organizations must comply with FACT Standards and policies throughout the duration of the accreditation cycle:
 - 6.1.1 Failure to comply with [Accreditation Process Policy](#), [Timelines for Organization Accreditation and Renewal](#), [Data Audit Policy](#), [Clinical Outcomes Corrective Action Plan Policy](#), and/or the requirements in this policy may result in suspension or termination of accreditation in accordance with [Suspension or Termination of Accreditation](#).
 - 6.1.2 The official public list of currently accredited organizations is located at www.factglobal.org.
- 6.2 Annual Report
 - 6.2.1 Organizations will receive an Annual Report notice on the 12-month anniversary of the current accreditation. The report will require organizational information; documentation of changes in key personnel, facilities, or services; and any additional documentation as required by the Accreditation Committee.

6.2.2 Organizations shall submit Annual Reports by the 13-month anniversary of the current accreditation.

6.2.2.1 If applicable, documentation of completion or implementation of corrective actions, as required by the Accreditation Committee, must be submitted.

6.2.3 If an Annual Report and required documentation are not received by the end of the 13-month anniversary of the current accreditation, the organization's accreditation may be suspended.

6.3 Additional Maintenance Requirements for Clinical Programs:

6.3.1 Clinical Programs must administer a minimum number of cellular therapy products to new patients as required by the applicable Standards.

6.3.1.1 For allogeneic hematopoietic cellular therapy accreditation, a minimum rolling average of ten (10) new allogeneic transplant recipients must be treated per year within the accreditation cycle. A clinical program accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation.

6.3.1.2 For autologous hematopoietic cellular therapy accreditation only, a minimum rolling average of five (5) new autologous transplant recipients must be treated per year within the accreditation cycle.

6.3.1.3 HCT programs utilizing more than one clinical site and/or performing adult and pediatric transplantation must transplant a minimum rolling average of five (5) new allogeneic patients (autologous patients if accredited for autologous only) at each site and each population per year.

6.3.1.4 For immune effector cellular (IEC) therapy accreditation only, the clinical program must administer cellular therapy products to a minimum rolling average of five (5) new recipients annually within the accreditation cycle.

6.3.1.5 For accreditation under the Common Standards for Cellular Therapies, the program must administer cellular therapy products to a minimum rolling average of five (5) new recipients annually within the accreditation cycle.

6.3.2 The clinical program must use products from collection and processing facilities that meet FACT Standards.

6.4 Additional Maintenance Requirements for Collection and Processing Facilities:

6.4.1 Collection facilities must use a processing facility that meets FACT Standards.

6.4.2 For HCT accreditation, marrow collection facilities must perform a minimum average of one (1) marrow collection procedure per year within the accreditation cycle.

6.4.3 For HCT accreditation, apheresis collection facilities must collect a minimum rolling average of ten (10) products by apheresis per year within the accreditation cycle.

- 6.4.4 The Apheresis Director must perform or supervise a minimum rolling average of five (5) cellular therapy product apheresis collection procedures per year within each accreditation cycle.
- 6.4.5 For HCT accreditation, the Processing Facility Director must perform or supervise a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.
- 6.5 Additional Maintenance Requirements for Cord Blood Banks:
- 6.5.1 At a minimum, the Cord Blood Bank must be actively distributing cord blood units.
- 6.6 Payment of annual fees is a requirement for continued accreditation
- 6.6.1 The accreditation of organizations with outstanding accreditation fees is suspended and the organization is removed from the FACT website until payment is received.
- 6.6.2 Accreditation and listing on the FACT website are restored after payment has been received.
- 6.7 Significant Change in an Accredited Organization
- 6.7.1 General Changes
- 6.7.1.1 Changes in an organization that require FACT notification within 90 days of the change but do not necessarily require an interim inspection of the organization may include, but are not limited to, a change in:
- Organization (or individual facility) name.
 - Qualified Program Director(s), Cord Blood Bank Director, or other facility director
 - Annexation of adjacent space within a single structure.
 - Addition or discontinuation of cord blood collection site(s).
 - Changes in ownership or mergers between accredited organizations unless changes result in issues described in 6.7.2, 6.7.3, or 6.7.4.
 - Changes to the organization as directed by applicable governmental agencies.
- 6.7.2 Facility Relocation
- 6.7.2.1 If an organization moves all or part of its facilities during an accreditation cycle, the organization must submit to FACT the following information within 90 days of the move:
- A description of the new facility(ies) including a floor plan and identification of the new location.

- New or revised policies and Standard Operating procedures (SOPs) required for the nature of the organization's relocation, as determined by the Chair of the Accreditation Committee or designee.
- Documentation of the relocation date and date of initiation of procedures at the new location.
- Documentation of assessments performed, including validations, revalidations, verifications, or qualifications that were performed due to the relocation, including a schedule for completing these assessments if not completed at the time of submission.

6.7.2.2 The Accreditation Committee Chair or designee will review the submitted documentation and determine if an interim inspection is required.

6.7.3 New Collection or Processing Facility

6.7.3.1 The accredited facility must notify FACT of its intentions to use a new collection or processing facility prior to use of that facility.

6.7.3.2 A new collection or processing facility, or one not yet accredited or not independently accredited will require a complete inspection.

6.7.3.3 A new collection or processing facility must have qualified personnel in place for at least twelve months preceding initial accreditation and must have performed the minimal number of procedures as defined in Standards.

6.7.3.4 The organization must propose to FACT a transition plan to use the new or not yet accredited collection or processing facility, including at a minimum:

- Length of time facility has been collecting and/or processing cellular therapy products.
- Number and types of cellular therapy products utilized by accredited clinical program(s) for the past year.
- Personnel qualifications including the number of qualified personnel and their relevant past work experience.
- Facility layout.
- Quality management plan.
- A proposed transition timeline.

6.7.3.5 FACT will review the transition plan and request changes as appropriate.

6.7.3.6 Accreditation of an organization using a collection or processing facility that has not been determined by FACT to meet all appropriate standards may be suspended or terminated.

6.7.4 Expansion of Services Offered

6.7.4.1 The organization must notify FACT of the following within 30 days of the service change:

- Addition of allogeneic transplantation to an accredited autologous transplantation program.
- Addition of adult transplantation to a pediatric program or pediatric transplantation to an adult program.
- Addition of clinical transplantation, collection, or processing services.
- Addition of clinical immune effector cellular therapy services.
- Addition of collection of new types of cellular therapy products.
- Addition of processing with more than minimal manipulation when accredited only for minimal manipulation or vice versa.
- Addition of cord blood collections performed at non-fixed sites when accredited only for cord blood collections at fixed sites or vice versa.
- Addition of banking of unrelated cord blood units to a bank accredited for the banking of related units only or vice versa
- Reestablishment of cord blood collection or processing services after a period of inactivity.

6.7.4.2 The Accreditation Committee Chair or designee will review the submitted documentation and timing of the accreditation cycle to determine the next steps and notify the organization.

6.7.4.3 If an interim inspection is required, FACT will provide the Compliance Application for the add-on services within 90 days.

6.7.5 Discontinuation of Services Offered

6.7.5.1 The organization must notify FACT within 90 days of discontinuation of any accredited services.

6.7.5.2 Cord blood banks that discontinue collection or processing, but continue distribution, must provide documentation of compliance with the applicable NetCord-FACT Standards within 90 days of discontinuation and within 90 days of resumption of operations. The Accreditation Committee Chair or designee will review the submitted documentation and timing of the accreditation cycle to determine if an interim inspection is required.

- 6.7.6 Changes in contractual service providers for collection or processing.
 - 6.7.6.1 The organization must notify FACT within 90 days after implementing these changes.
 - 6.7.6.2 Contractual service providers must be FACT accredited or determined by FACT to meet applicable FACT standards.
- 6.7.7 The accredited organization must notify FACT within 90 days of changes due to a natural disaster.

6.8 Interim Inspection

- 6.8.1 An interim inspection may be a complete or focused inspection of an accredited organization occurring within an accreditation cycle. An interim inspection may be required if:
 - 6.8.1.1 FACT receives information that indicates an organization may be out of compliance with the FACT Standards. Refer to [Hearsay Evidence](#) and [Reviewing Complaints and Grievances](#).
 - 6.8.1.2 A significant change in the accredited organization's structure occurs as defined in section 6.7 of this policy.
- 6.8.2 If an interim inspection is deemed necessary, the following will occur:
 - 6.8.2.1 If the interim inspection is scheduled to occur within twelve months of the organization's accreditation expiration date, a complete inspection of the accredited organization may be conducted.
 - The organization will be inspected under the current edition of the FACT Standards.
 - A new accreditation expiration date for the organization will be adjusted if a full interim inspection was conducted.
 - 6.8.2.2 If the interim inspection is scheduled to occur more than twelve months prior to the organization's accreditation expiration date, a focused inspection of the accredited organization's facilities that have undergone significant change may be conducted.
 - This reinspection will be designed to ensure all FACT Standards directly related to the reported change(s) are met and that procedures or mechanisms previously approved by FACT remain in place.
 - The organization will be inspected under the current edition of the FACT Standards and will pay a fee based on the number of inspectors required.
 - The accreditation expiration date for the organization will not be adjusted if a focused inspection is conducted.

- A full inspection will occur at the appropriate time in the organization's accreditation cycle.

6.8.3 An organization that has had a significant change involving relocation, addition of services, change in contractual service providers, and/or organizational restructuring sufficient to require an interim inspection visit must complete the reaccreditation process within twelve months of the change.

Approved by (date):

Heather Conway (Quality Manager) (03/September/2023), Phyllis Warkentin (Chief Medical Officer) (03/September/2023)