Maintaining Accreditation

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 is applicable to organizations accredited by FACT.

3.0 Responsibility

3.1 It is the responsibility of the FACT Office 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 Hearsay Evidence, 4.1.001
4.2 Reviewing Complaints and Grievances, 4.2.001
4.3 Accreditation Process, 6.1.001
4.4 Timelines for Organization Accreditation and Renewal, 6.2.001
4.5 Suspension or Termination of Accreditation, 6.1.005
4.6 Past Due Annual Invoices, 1.4.011
4.7 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration
4.8 FACT Common Standards for Cellular Therapies
4.9 FACT Standards for Immune Effector Cells
4.10 NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration

5.0 Definitions

5.1 **Organization**: Refers to cord blood banks, clinical programs, cell collection facilities, and/or cell processing facilities undergoing accreditation by FACT. An organization consists of the facilities, personnel, policies, procedures, and records.

5.2 **FACT Accreditation Committee**: Refers to either the cord blood bank or cellular therapy program accreditation committee as described in this policy, as applicable.

Document Approvals

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Date Approved: 17Jan2018

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Date Approved: 18Jan2018

5.3 **Interim Inspection**: An on-site inspection of an accredited organization made outside of the routine accreditation process.

5.3 **Facility:** A location where activities covered by the accreditation process and applicable standards are performed.

5.4 **Suspension of Accreditation:** Organization will not be accredited and will be removed from the website pending resolution of issue. Upon resolution of issue, accreditation will be reinstated without a change in expiration date.

5.5 **Termination of Accreditation:** Organization's accreditation will be revoked and a reapplication and completion of the accreditation process will be required to regain accreditation.

5.6 **Annual Accreditation Fee:** Annual fee set forth according to the current fee structure available on FACTwebsite.org.

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 policies, Accreditation Process (6.1.001); Timelines for Organization Accreditation and Renewal (6.2.001); and/or the requirements in this policy may result in suspension or termination of accreditation in accordance with the Suspension or Termination of Accreditation Policy (6.1.005).

6.1.2 The official public list of currently accredited organizations is located on FACTwebsite.org.

6.2 Annual Reports

6.2.1 Organizations will receive an Annual Report notice on the 12 month anniversary of the current accreditation. The report will request organizational information and any additional documentation as required.

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 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 hematopoietic cellular therapy (HCT) allogeneic accreditation, a minimum average of ten new allogeneic patients must be transplanted 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 HCT autologous accreditation only, a minimum average of five new autologous patients must be transplanted 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 perform transplants on a minimum average of five new allogeneic patients (autologous patients if accredited for autologous only) at each site and of each population per year.

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

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

6.3.2 The program must use products from collection and processing facilities that meet requirements for collection and processing as specified in the applicable set of Standards.

6.4 Additional Maintenance Requirements for Collection and Processing Facilities:

6.4.1 Collection Facilities must use a facility that meets requirements for processing as specified in the applicable set of Standards.

6.4.2 For HCT accreditation, apheresis collection facilities must collect a minimum average of 10 products by apheresis per year within the accreditation cycle.

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

6.4.4 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.

6.4.5 Additional Maintenance Requirements for Cord Blood Banks:

6.4.5.1 Must be actively distributing cord blood units.

7.0 Payment of annual fees is a requirement for continued accreditation

7.1 Organizations with outstanding accreditation fees are removed from the FACT website and their accreditation is suspended until payment is received. Refer to Past Due Annual Invoices policy (1.4.011).

7.2 Accreditation and listing on the FACT website are restored after payment has been received.

8.0 Significant Change in an Accredited Organization

8.1 General Changes

8.1.1 Changes in an organization that require FACT notification within 90 days of the change but do not require an interim inspection of the organization may include, but are not limited to, a change in:

8.1.1.1 Organization (or individual facility) name.

8.1.1.2 Qualified Program Director(s), Cord Blood Bank Director, or other facility director.

8.1.1.3 Annexation of adjacent space within a single structure.

8.1.1.4 Addition or discontinuation of cord blood collection site(s).

8.1.1.5 Changes in ownership or mergers between accredited organizations unless changes result in 8.2, 8.3, or 8.4.

8.1.1.6 Changes to the organization as directed by applicable governmental agencies.

8.2 Facility Relocation

8.2.1 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:

8.2.1.1 A description of the new facility(ies) including a floor plan and identification of the new location.

8.2.1.2 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.

8.2.1.3 Documentation of the date relocation occurred and when processes were started at the new location.

8.2.1.4 Documentation of assessments performed, including validations, revalidations, verifications, or qualifications that were performed due to the relocation. Include a schedule for completing these assessments if these assessments were not completed at the time of submission.

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

8.3 New Collection or Processing Facility

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

8.3.2 A new collection or processing facility not yet accredited or not independently accredited will require a complete inspection against applicable standards.

8.3.2.1 A new collection facility must have qualified personnel in place as required by the Standards for at least 12 months prior to accreditation.

- A Marrow Collection Facility must have performed one marrow collection procedure in the 12 months preceding accreditation.
- An Apheresis Collection Facility must have performed a minimum of ten (10) cellular therapy product collections by apheresis in the 12 months preceding accreditation.

8.3.2.2 A new processing facility must have qualified personnel in place as required by the Standards for at least 12 months prior to accreditation.

8.3.3 The organization must propose a transition plan to FACT that includes the following, at a minimum:

8.3.3.1 Length of time facility has been collecting and/or processing cellular therapy products.

8.3.3.2 Number and types of cellular therapy products utilized by accredited clinical program(s) for the past year.

8.3.3.3 Number and types of cellular therapy products proposed for use by accredited clinical program(s) going forward.

8.3.3.4 Personnel qualifications including the number of qualified personnel and their relevant past work experience.

8.3.3.5 Facility layout.

8.3.3.6 Quality management plan.

8.3.3.7 A timeline that outlines when FACT can expect progress reports regarding the transition. The timeline must be approved by FACT.

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

8.3.5 An organization not using a collection and processing facility that has been determined by FACT to meet all appropriate standards will be suspended or terminated.

8.4 Expansion of Services Offered

8.4.1 The organization must notify FACT of the following within 30 days after the service change (including but not limited to):

8.4.1.1 Addition of allogeneic transplantation to an autologous transplantation program.

8.4.1.2 Addition of adult transplantation to a pediatric program or pediatric transplantation to an adult program.

8.4.1.3 Addition of clinical, collection, or processing services.

8.4.1.4 Addition of clinical immune effector cellular therapy services.

8.4.1.5 Addition of collection of new types of cellular therapy products (e.g., HPCs, MSCs, DCs).

8.4.1.6 Addition of processing with more than minimal manipulation when accredited only for minimal manipulation or vice versa.

8.4.1.7 Addition of cord blood collections performed at non-fixed sites when accredited only for cord blood collections at fixed sites or vice versa.

8.4.1.8 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.

8.4.2 FACT will provide the organization with a list of service expansion related documentation that must be submitted within 90 days after the service change.

8.4.3 The Accreditation Committee or designee will review the submitted documentation and timing of the accreditation cycle to determine if an interim inspection is required.

8.5 Discontinuation of Services Offered

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

8.5.2 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 or designee will review the submitted documentation and timing of the accreditation cycle to determine if an interim inspection is required.

8.6 Changes in contractual service providers for collection or processing.

8.6.1 The organization must notify FACT within 90 days of implementing these changes.

8.6.2 Contractual service providers must be FACT accredited or determined by FACT to meet applicable FACT standards.

8.7 Changes due to a natural disaster.

8.7.1 The organization must notify FACT within 90 days of the event.

9.0 Interim Inspection

9.1 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:

9.1.1 FACT receives information that indicates an organization may be out of compliance with the FACT Standards. Refer to Hearsay Evidence (4.1.001) and Reviewing Complaints and Grievance (4.2.001).

9.1.2 A significant change in the accredited organization's structure occurs as defined in section 1.0 of this policy.

9.2 If an interim inspection is deemed necessary, the following will occur:

9.2.1 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 will be conducted.

9.2.1.1 The organization will be fully inspected under the current edition of the FACT Standards.

9.2.1.2 The new accreditation expiration date for the organization will be adjusted to reflect completion of the full reinspection of the accreditation process.

9.2.2 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 will be conducted.

9.2.2.1 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.

9.2.2.2 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.

9.2.2.3 The accreditation expiration date for the organization will not be adjusted to reflect the focused reinspection.

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

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

9.0 Revision History

Date	Revision #	Author/Requestor	Changes	Justification
04Jun2008	0	Chief Medical Officer	New Document	New Document
14Sep2009	1	Manager, Standards Development and Training	1.Add section regarding the termination or suspension of accreditation status for non-specific issues, including how the decision is made and what the appeals process is. 2. Include Cord Blood Banks in policy and adjust title of policy accordingly.	1. Current SOPs only address termination or suspension of FACT accreditation for specific issues, such as missing a deadline to submit an interim report. General steps need to be included for a comprehensive policy to include termination/suspension due to grievances, sentinel events, or any other issue that may arise for which the Board feels termination or suspension of accreditation is necessary. 2. This policy is applicable to both CT programs and Cord Blood Banks.
28Apr2011	2	Manager, Standards Development and Training	1. Change title of policy to "Maintaining Accreditation" 2. Sections 6, 7, 8, and 10 have been added to this policy from 6.1.001. The accreditation status granted to organizations has moved to 6.1.001	1. This title is more inline with FACT's policy format and allows constituents to more easily reference information. 2. 6.1.001 focuses on the initial accreditation process, and the policy information has been moved accordingly. The content has been moved, but not changed.
27Sep2012	3	Director of Operations	1. Update number of transplants to number per accreditation cycle. 2. Add definitions for Suspension and Termination of Accreditation. 3. Remove 7.1.1.3 and 7.1.1.4 per CMO's request. 4. Add new collection and processing facilities section regarding new cell types to define requirements for a new facility. 5. Update appendix I to include numbers per accreditation cycle.	These changes are needed due to changes in time-frames for transplant requirements and for clarification purposes.
27Feb2013	4	Director of Operations	1. Notification of use of new collection or processing facility prior to FACT inspection. 2. Add additional factors to consider when transitioning to a new facility. 3. Remove Suspension/Termination of Organizations sections to stand-alone policy.	1. and 2.When programs us a facility that has never been inspected by FACT, especially brand-new facilities, there are certain issues that should be taken into account for the transition plan. The changes require notification to FACT before using a new facility, and also require the program to consult with FACT regarding the transition plan. 3. Sections should be in separate, easier-to-find policy for constituents.
14Aug2013	5	Director of Operations	Clarified that failure to comply with key accreditation policies may result in suspension or termination. Referenced appropriate policies	Clarify to applicants the consequence of not meeting accreditation maintenance requirements.
07Mar2018	6	Director of Operations	Described steps to take when cord blood collection or processing is discontinued. Annual fees must be paid to maintain accreditation. Remove appendix with minimum number of transplants per accreditation cycle. Addition of references to newer sets of Standards/accreditation services as applicable. General editorial changes	Clarify reporting responsibilities of cord blood banks at the time of discontinuation and of reestablishment of collection or processing. Need to include that payment of annual fees is a requirement to maintain FACT accreditation. The official number of transplants per accreditation cycle is listed in the applicable Standards and the Standards are the primary source of this information. This policy also applies to accreditation under the Common and IEC Standards Improve accuracy and clarity