 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER Policies and Procedures</p>	<p><b>Policy</b></p>	<p>Document #: 6.1.001 Revision: 8 Publication Date: 8/30/2019 Page 1 of 15 Effective Date: 8/30/2019</p>
<p><b>Accreditation Process</b></p>		

**1.0 Purpose**

This policy establishes guidelines for the FACT accreditation process.

**2.0 Scope**

This policy is applicable to FACT personnel and volunteers, and applicant organizations.

**3.0 Responsibility**

3.1 It is the responsibility of FACT to ensure that:




- 3.1.1 All FACT personnel and volunteers, and applicant organizations have access to this policy.
- 3.1.2 The policy is followed.

**4.0 References**

- 4.1 Maintaining Accreditation, 6.1.003
- 4.2 Suspension or Termination of Accreditation, 6.1.005
- 4.3 Timelines for Organization Accreditation and Renewal, 6.2.001
- 4.4 Review of Accreditation Applications and Annual Reports, 6.6.002
- 4.5 Cord Blood Facility Site Grid, 6.6.002 Form 4
- 4.6 Initial FACT Inspector Qualifications, 7.1.001
- 4.7 Inspector Training Program, 7.2.002

**5.0 Definitions**

- 5.1 **Organization:** Clinical program, cellular therapy collection facility, cellular therapy processing facility, cord blood bank, cord blood collection site, or cord blood processing facility that has achieved or is applying for FACT accreditation.
- 5.2 **Eligibility Application:** Online form that includes information necessary to determine an organization’s eligibility for initial accreditation, define its accreditation goals, and generate the Compliance Application.

<p>Document Approvals:</p>		
 Chief Medical Officer Phyllis Warkentin Date Approved: 8/29/2019	 Chief Executive Officer Linda Miller Date Approved: 8/29/2019	 Quality Manager Heather J. Conway Date Approved: 8/29/2019

- 5.3 **Compliance Application:** Online form that includes information and documentation necessary to demonstrate compliance with the FACT Standards. This form contains all applicable FACT Standards and is used to evaluate an organization throughout the inspection and accreditation process.
- 5.4 **Annual Report:** Online form that includes documentation of an organization's continued compliance with FACT Standards and accreditation requirements during the accreditation cycle.
- 5.5 **Renewal Report:** Online form that includes information and documentation necessary to determine eligibility for renewal accreditation, define the renewal accreditation goals, and generate the Compliance Application.
- 5.6 **Accreditation Goal:** the services(s) provided by an applicant organization for which accreditation is sought.
  - 5.6.1 All services provided by an organization under the same name and directorship must be part of the accreditation goal.

## 6.0 Accreditation Process

### Application for Accreditation

- 6.1 An organization applying for accreditation must complete the process within the timelines defined in the policy *Timelines for Organization Accreditation and Renewal*, 6.2.001.
  - 6.1.1 An organization seeking initial accreditation must submit the Compliance Application within 12 months of determination of eligibility and must complete the accreditation process within 12 months of submission of the Compliance Application.
  - 6.1.2 An organization applying for renewal accreditation must complete the process prior to the expiration of its current accreditation.
- 6.2 An organization applying for initial or renewal accreditation must submit the applicable online application.
  - 6.2.1 An organization applying for initial accreditation submits an Eligibility Application and the nonrefundable application fee.
  - 6.2.2 An organization applying for renewal accreditation submits a Renewal Report.
- 6.3 The Accreditation Services Supervisor or designee reviews the Eligibility Application or Renewal Report for completeness and eligibility for FACT accreditation in accordance with procedure *Review of Accreditation Applications and Annual Reports*, 6.6.002.
  - 6.3.1 An ineligible organization may be eligible to receive a partial application fee refund.
  - 6.3.2 Refer to the FACT Accreditation Fees page for all accreditation fees:  
[http://www.factwebsite.org/Accreditation\\_Process/Fees.aspx](http://www.factwebsite.org/Accreditation_Process/Fees.aspx)

- 6.4 The Accreditation Committee Chair or designee may determine that an organization is ineligible for accreditation.
  - 6.4.1 If determined to be ineligible, the organization will be informed in writing, including an explanation of ineligibility.
  - 6.4.2 If the organization disagrees with this decision, the decision may be appealed in writing within 30 days of receipt of denial. The organization submits the appeal to the FACT Chief Medical Officer who will make the eligibility determination in consultation with the FACT Board of Director's President or designee.
  - 6.4.3 The applicant organization will be notified of the decision.
  - 6.4.4 The organization may appeal the decision to the full Board of Directors by submission of the appeal within 30 days of notification, except as defined in 6.4.5.
  - 6.4.5 There is no right to further appeal if the determination of the organization's ineligibility is based upon any of the following:
    - 6.4.5.1 The application is incomplete.
    - 6.4.5.2 The Director(s) or the organization does not meet the minimum qualifications defined in the Standards.
    - 6.4.5.3 The threshold number of procedures has not been performed or the threshold number of cord blood units has not been banked.
- 6.5 If eligible for accreditation, the organization will be sent instructions for the accreditation process.
- 6.6 The applicant completes and submits the Compliance Application and supporting documents.
- 6.7 Based on review by the FACT Accreditation Coordinator, the organization may be required to submit additional or clarifying information.
- 6.8 When the Compliance Application is acceptable, including uploaded documentation, an inspection team will be assigned.

### **General Inspection Guidelines**

- 6.9 The inspection team is chosen from the eligible pool of inspectors and trainees. The team members are experienced and trained in the areas to be inspected in accordance with SOPs *Initial FACT Inspector Qualifications, 7.1.001* and *Inspector Training Program, 7.2.002*.
  - 6.9.1 The size and complexity of the facility's operations determines the number of inspectors assigned.
  - 6.9.2 Inspection team members are not affiliated with an organization in direct economic competition with or located within the same metropolitan statistical area of the applicant organization. Whenever possible, inspection team members are affiliated with an organization at least 500 miles away from the organization.
- 6.10 Inspectors do not inspect the same organization more often than every two inspection cycles (i.e., six years). Reciprocal inspections will not occur within the span of two regularly scheduled inspection cycles.

- 6.10.1 A reciprocal inspection is one in which an inspector inspects an applicant organization that employs a prior inspector of his or her organization.
- 6.11 The proposed inspection team is approved by the FACT Chief Medical Officer.
- 6.12 The applicant organization is informed of the names of the inspectors approximately 60 days prior to the inspection. If the Director has objections regarding the qualifications or objectivity of an inspector, notification must be submitted within five business days of receiving notice of the proposed inspectors. The FACT Chief Medical Officer will review the objection. If determined to have merit, a new inspector may be assigned.
- 6.13 The FACT Chief Medical Officer appoints a member of the inspection team as the leader. It is the responsibility of the team leader to set the agenda for the inspection, to ensure the inspection is completed according to FACT policies and Standard Operating Procedures, and, in conjunction with the team members, to complete and submit inspection reports on-line in a timely manner (refer to step 6.24).
- 6.14 Any facilities that are associated with but are at a separate location from the organization should be inspected before or during the main inspection to ensure the inspection team has adequate time to discuss any deficiencies that may be cited at the separate locations. The entire inspection should be completed prior to the exit interview.
- 6.15 The Director will ensure that the inspection is scheduled for a date when key organization personnel will be available to interact with the inspection team. In addition to the Program or Cord Blood Bank Director (as applicable), the other Director(s) and Medical Director(s), and the Quality Manager(s) must be available.
  - 6.15.1 If possible, the inspection should be scheduled on a day when there will be procedures being performed to permit the inspectors to observe staff performing the procedures.
    - 6.15.1.1 If no procedures are occurring on the day of the inspection, the organization should demonstrate a mock collection or processing event for the inspection team.
  - 6.15.2 The Directors must be available during the inspection, but may assign a designee to be responsible for coordination of the inspection, including answering questions, escorting the inspection team, and retrieving any documents the team may need.
- 6.16 Each inspection team member completes the Compliance Application for the area(s) for which he/she is responsible. The team members confer as appropriate to reach decisions on issues that are unclear or span more than one area.
- 6.17 At the conclusion of the inspection, the team will meet with the relevant Directors and other key personnel and present a summary of major findings, including significant items they expect to list as potential deficiencies.
- 6.18 The inspectors' entries in the Compliance Application are submitted electronically to FACT. The inspection team's conclusions are recommendations to the Accreditation Committee.

## Unique Inspection Requirements

- 6.19 Inspection of clinical programs.
  - 6.19.1 All cellular therapy services provided by the Clinical Program must be inspected. This includes but is not limited to therapies administered on the inpatient unit, in the outpatient facility, or under the supervision of the program's attending physicians.
    - 6.19.1.1 Cellular therapy services added during an accreditation cycle are inspected during the renewal accreditation process. If the program wishes to be accredited for the new services prior to that time, the service may be added to the accreditation in accordance with the add-on service process, and the applicable fees apply.
  - 6.19.2 Immune effector or cellular therapies provided in a different clinical service, but in the same institution as the accredited bone marrow transplant program, are accredited and inspected as follows:
    - 6.19.2.1 If the service has the same Director, QM Program, and SOPs, it will be considered an additional site, and the additional site fee applies.
    - 6.19.2.2 The therapy provided by the service will be added to the accreditation in accordance with the add-on service process, and the applicable fees will apply.
    - 6.19.2.3 If the service has a different Director or QM Program, it must apply for separate accreditation.
    - 6.19.2.4 FACT Chief Medical Officer will determine accreditation structure for unique situations.
  - 6.19.3 Facilities participating in the collection or processing of cellular therapy products used by the accredited clinical program must be inspected. This excludes commercial manufacturers under regulatory oversight.
- 6.20 Contracted cellular therapy facilities (e.g., collection and/or processing) have two options for accreditation:
  - 6.20.1 Be inspected with each clinical program it serves and only be accredited in relationship to the program(s), or,
  - 6.20.2 Pursue independent accreditation when serving multiple clinical programs.
- 6.21 Inspection of collection facilities.
  - 6.21.1 All cell collection services must be inspected. This includes collection of products for use in the accredited clinical program and those collected for further manufacturing only.
  - 6.21.2 Inspection of marrow collection facilities associated with an accredited or applicant clinical program.
    - 6.21.2.1 Marrow collection facilities that perform the minimum number of marrow collections for FACT accreditation are required to meet all marrow collection standards and be inspected.

- 6.21.2.2 Marrow collection facilities that perform marrow collections but do not perform the minimum number of marrow collections for FACT accreditation are required to meet all marrow collection standards and be inspected, though they are not eligible for FACT accreditation.
- 6.22 Inspection of cellular therapy processing facilities performing cellular therapy product processing with more than minimal manipulation.
- 6.22.1 Processing facilities performing cellular therapy processing with both minimal and more than minimal manipulation must be inspected for both of these activities.
  - 6.22.2 More than minimal manipulation activities performed in the same facility as minimal manipulation are inspected and accredited together.
  - 6.22.3 Activities performed in a different facility, but in the same institution of the accredited facility, are accredited and inspected as follows:
    - 6.22.3.1 If the facility has the same Director, QM Program, and SOPs, it will be considered an additional site, and the additional site fee applies.
    - 6.22.3.2 Activities added to the accredited facility's processes will be inspected during the renewal accreditation process. If the facility wishes to be accredited for the new activities prior to that time, it will be added to the accreditation in accordance with the add-on service process, and the applicable fees apply.
    - 6.22.3.3 If the facility has a different Director or QM Program, it must apply for separate accreditation.
- 6.23 Inspection of cord blood sites.
- 6.23.1 Cord Blood Banks requesting accreditation for cord blood banking must meet the Cord Blood Standards at each site.
  - 6.23.2 To facilitate the inspection of a bank's processing facilities, off-site storage facilities, and collection sites, organizations are required to complete the *Cord Blood Facility Site Grid, 6.6.002 Form 4*, to provide detailed information on each site.
  - 6.23.3 All processing and off-site storage facilities are inspected.
  - 6.23.4 If more than one collection site exists, FACT will determine the minimum number of collection sites to be inspected based on the total number of collection sites performing services for the bank:
    - 6.23.4.1 Two sites will be inspected for up to five total collection sites.
    - 6.23.4.2 Three sites will be inspected for up to ten total collection sites.
    - 6.23.4.3 Four sites will be inspected for up to 20 total collection sites.
    - 6.23.4.4 Five sites will be inspected for up to 50 total collection sites.
    - 6.23.4.5 Seven sites will be inspected for up to 100 total collection sites.
    - 6.23.4.6 Nine sites will be inspected for 101 or more total collection sites.
  - 6.23.5 FACT selects which collection sites will be inspected to include at least one example of each of the variables included on the Cord Blood Bank Facility Site Grid.

- 6.23.6 The FACT Accreditation Coordinator, with approval from the FACT Chief Medical Officer, uses the aforementioned criteria to select a variety of collection sites to be inspected.
- 6.23.7 For non-fixed collection sites, materials (e.g. recruitment, consent, training, SOPs); management of supplies, reagents, and collected cord blood units and tissue; the collection process; and quality data are inspected.
  - 6.23.7.1 Non-fixed collection sites that collect 52 or more cord blood units in a year are subject to on-site inspection and are included in the algorithm described in 6.23.4.
- 6.23.8 Cord Blood Banks must be inspected and accredited for any type of donation accepted (unrelated or related), even if rarely accepted.
- 6.23.9 Discontinuation of cord blood collection or processing.
  - 6.23.9.1 Cord Blood Banks must notify FACT upon discontinuation of collection or processing activities in accordance with the policy *Maintaining Accreditation, 6.1.003*. Initial accreditation is not awarded unless both collection and processing services are active.
  - 6.23.9.2 Cord Blood Banks must comply with the NetCord-FACT Standards related to interruption of operations at established sites.
  - 6.23.9.3 Upon reinstatement of collection or processing activities, the Cord Blood Bank must notify FACT in accordance with the policy, *Maintaining Accreditation, 6.1.003*.

### **Review of Inspection Results**

- 6.24 Inspector reports are submitted electronically to FACT within two weeks of the completion of the inspection.
- 6.25 Inspection team members should submit their individual reports to the inspection team leader within three days of the inspection for review and compilation.
- 6.26 The FACT Accreditation Coordinators review the submitted inspector reports and prepare an accreditation report for the Accreditation Committee.
- 6.27 Accreditation reports are available to the Accreditation Committee one week prior to the Accreditation Committee meeting.
  - 6.27.1 All Accreditation Committee members are expected to review each report.
  - 6.27.2 An inspector (or Accreditation Committee member if the inspector is unavailable) may be assigned as the primary reviewer of a report if that report meets any of the following criteria:
    - 6.27.2.1 The report is a response that the Accreditation Committee has requested be re-evaluated by the committee.
    - 6.27.2.2 The report contains an excessive number of citations (>20) in one area (e.g., either one facility or quality management).

- 6.27.3 The primary reviewer is responsible for:
  - 6.27.3.1 Reviewing the report, previous reports, and additional documentation as appropriate prior to the committee meeting.
  - 6.27.3.2 Requesting additional information from the FACT Accreditation Coordinator as necessary to fully understand the report.
  - 6.27.3.3 Making recommendations to the committee concerning the adequacy of the response or the appropriateness of the citations.
- 6.27.4 If the primary reviewer does not believe there is sufficient information to make an informed decision, the report will not be discussed by the committee until sufficient information has been received.
- 6.28 The Accreditation Committee reviews the report to determine a recommended accreditation outcome:
  - 6.28.1 Accreditation awarded to an organization when there were no deficiencies or variances observed during the on-site inspection and all submitted documents demonstrate compliance with the Standards.
    - 6.28.1.1 Initial accreditation is effective on the date of the Accreditation Committee's decision and effective for three years.
    - 6.28.1.2 Renewal accreditation is effective on the three-year anniversary date.
    - 6.28.1.3 Extenuating circumstances may dictate the accreditation date as described below and in the policy, *Timelines for Organization Accreditation and Renewal, 6.2.001*.
  - 6.28.2 Accreditation, pending correction of deficiencies and additional documentation.
    - 6.28.2.1 Documentation by the organization of correction of all deficiencies and a satisfactory response to all variances from recommendations is required.
    - 6.28.2.2 Each variance noted during an inspection requires a response from the Director stating the rationale for the practice, but no procedural changes are required of the organization.
    - 6.28.2.3 Time Interval: 60 days or prior to expiration date.
    - 6.28.2.4 In cases where correction may require additional time, documentation of planned correction may be accepted (e.g., blueprint of new space with a letter documenting resource allocation). Documentation of completion of the plan or progress towards completion is required at the time of annual report.
    - 6.28.2.5 The Accreditation Committee Chair determines the adequacy of the response and may award full accreditation without further Accreditation Committee review. Incomplete or unsatisfactory responses may be referred back to the Committee.



- 6.28.2.6 In the event that all documentation is not received or is deemed incomplete by the Accreditation Committee Chair within this time period, the organization may have its FACT Accreditation suspended or terminated per policy *Suspension or Termination of Accreditation, 6.1.005*,
  - 6.28.2.7 For organizations seeking initial accreditation, if the accreditation process takes significantly longer than normal, as determined by the Accreditation Committee, the period of accreditation may be shortened to 3 years from the initial on-site inspection date.
- 6.28.3 Accreditation, pending Accreditation Committee re-evaluation.
- 6.28.3.1 Significant deficiencies were noted at the on-site inspection.
  - 6.28.3.2 Documentation by the organization of correction of all deficiencies and satisfactory response to variances from recommendations is required.
  - 6.28.3.3 The Accreditation Committee reviews the documented corrections and responses prior to making an accreditation decision. In cases where correction may require additional time, documentation of planned correction will be accepted (e.g. blueprint of new space with a letter documenting resource allocation). Documentation of completion of the plan or the progress towards completion is required at the time of the annual or renewal report.
  - 6.28.3.4 Each variance noted during an inspection requires a response from the Director stating the rationale for the practice, but no procedural changes are required of the organization.
  - 6.28.3.5 The Committee may require reinspection of all or part of an organization or facility based upon the adequacy of responses submitted.
  - 6.28.3.6 Time Interval: 90 days or prior to the expiration date, whichever is earliest.
  - 6.28.3.7 In the event that all documentation is not received or is deemed incomplete by the Accreditation Committee within this time period, the organization may have its FACT accreditation suspended or terminated per policy *Suspension or Termination of Accreditation, 6.1.005*.
  - 6.28.3.8 For organizations seeking initial accreditation, if the accreditation process takes significantly longer than normal, as determined by the Accreditation Committee, the period of accreditation period may be shortened to 3 years from the initial on-site inspection date.
- 6.28.4 Partial Focused Reinspection
- 6.28.4.1 Major and systemic deficiencies were observed at the on-site inspection, primarily involving one or two areas in the organization.
  - 6.28.4.2 Full accreditation requires correction of all deficiencies, written documentation of these corrections, a satisfactory response to all variances from recommendations, and satisfactory completion of a focused reinspection of a portion of an organization. A new inspector or team may be assigned or the previous inspector or team may be used, if appropriate. A new Compliance Application is not required.

- 6.28.4.3 In the event a new edition of Standards is published between the time an organization was initially inspected and a required focused reinspection is conducted, the organization is automatically required to undergo the focused reinspection under the new edition of Standards.
  - 6.28.4.4 There is a reinspection fee as determined by FACT.
  - 6.28.4.5 The results of the partial focused reinspection are reviewed by the Accreditation Committee, who determines the accreditation status of the organization.
  - 6.28.4.6 Time Interval: 90 days to submit complete response and schedule the reinspection. The reinspection must occur within 90 days of submitting the response.
  - 6.28.4.7 The organization's FACT accreditation will be suspended or terminated after the expiration date per policy *Suspension or Termination of Accreditation, 6.1.005*.
  - 6.28.4.8 In the event that that the organization does not schedule its reinspection within the required time period, all documentation is not received, or the documentation is deemed incomplete by the Chair of the Accreditation Committee, the organization may have its FACT accreditation suspended or terminated. Organizations not previously accredited may be required to undergo a complete reinspection and submit additional fees if these requirements are not met.
  - 6.28.4.9 Following reinspection and Accreditation Committee review, the organization will be responsible for completing the process in the time interval based on the current accreditation status recommended by the Accreditation Committee.
  - 6.28.4.10 In cases where correction may require additional time, documentation of planned correction may be accepted (e.g., blueprint of new space with a letter documenting resource allocation). Documentation of completion of the plan or the progress towards completion is required at the time of annual or renewal reporting.
  - 6.28.4.11 Each variance noted during an inspection requires a response from the Director stating the rationale for the practice, but no procedural changes are required of the organization.
  - 6.28.4.12 For organizations seeking initial accreditation, if the process of application, inspection, and review takes significantly longer than normal, as determined by the Accreditation Committee, the period of accreditation may be reduced to three years from the date of the initial on-site inspection.
- 6.28.5 Full Focused Reinspection
- 6.28.5.1 Major and systemic deficiencies were observed during the on-site inspection involving all areas of an organization. Full accreditation requires correction of all deficiencies, written documentation of these corrections, a satisfactory response to all variances from recommendation, and satisfactory completion of a focused reinspection of all areas of the organization. A new Compliance Application is not required.

- 6.28.5.2 In the event a new edition of Standards is published between the time an organization was initially inspected and a required focused reinspection is conducted, the organization is automatically required to undergo the focused reinspection under the new edition of Standards.
  - 6.28.5.3 There is a reinspection fee as determined by FACT.
  - 6.28.5.4 The results of the full focused reinspection are reviewed by the Accreditation Committee, who determines the accreditation status of the organization.
  - 6.28.5.5 Time Interval: 90 days to submit complete response and schedule the reinspection. The reinspection must occur within 90 days of submitting the response.
  - 6.28.5.6 The organization's FACT accreditation is suspended or terminated after the expiration date per policy *Suspension or Termination of Accreditation, 6.1.005*.
  - 6.28.5.7 In the event that that the organization does not schedule its reinspection within the required time period, all documentation is not received, or the documentation is deemed incomplete by the Chair of the Accreditation Committee, the applicant's FACT accreditation is suspended or terminated. Organizations not previously accredited may be required to undergo a complete reinspection and submit additional fees if these requirements are not met.
  - 6.28.5.8 Following reinspection and Accreditation Committee review, the organization is responsible for completing the process in the time interval based on the determination of the Accreditation Committee.
  - 6.28.5.9 In cases where correction may require additional time, documentation of planned correction may be accepted (e.g., blueprint of new space with a letter documenting resource allocation). Documentation of completion of the plan or the progress towards completion is required at the time of the annual or renewal report.
  - 6.28.5.10 Each variance noted during an inspection requires a response from the Director stating the rationale for the practice, but no procedural changes are required of the organization.
  - 6.28.5.11 For organizations seeking initial accreditation, if the process of application, inspection, and review takes significantly longer than normal, as determined by the Accreditation Committee, the period of accreditation may be reduced to three years from the date of the initial on-site inspection.
- 6.28.6 Complete Reinspection
- 6.28.6.1 The organization does not meet the requirements for FACT accreditation. The accreditation of the organization is suspended or terminated on the day of the Accreditation Committee decision until the organization demonstrates compliance with all applicable FACT Standards in accordance with policy *Suspension or Termination of Accreditation, 6.1.005*.

- 6.28.6.2 Eligibility requirements must be met prior to a complete reinspection of the organization. A new Compliance Application is required.
  - 6.28.6.3 In the event a new edition of Standards is published between the time an organization was initially inspected and a required complete reinspection is conducted, the organization is automatically required to undergo the reinspection under the new edition of Standards.
  - 6.28.6.4 There is a reinspection fee as determined by FACT.
  - 6.28.6.5 Time Interval: 12 months to submit all required documents and schedule the reinspection. The reinspection must occur within 180 days of submitting the response.
  - 6.28.6.6 The results of the complete reinspection is reviewed by the Accreditation Committee, who determine the accreditation status of the organization.
  - 6.28.6.7 Following reinspection and Accreditation Committee review, the organization is responsible for completing the process in the time interval determined by the Accreditation Committee.
  - 6.28.6.8 In cases where correction may require additional time, documentation of planned correction may be accepted (e.g. blueprint of new space with a letter documenting resource allocation). Documentation of the progress towards completion or completion of the plan is required at the time of the annual or renewal report.
  - 6.28.6.9 Each variance noted during an inspection requires a response from the Director stating the rationale for the practice, but no procedural changes are required of the organization.
  - 6.28.6.10 The accreditation date is the date of completion of the current accreditation process.
- 6.29 The Accreditation Committee submits accreditation recommendations to the Board of Directors.
- 6.29.1 If the Accreditation Committee is unable to reach a consensus for a decision, the Board of Directors will make the final determination.
  - 6.29.2 The Board of Directors reviews, approves, or denies the Accreditation Committee recommendations.
  - 6.29.3 The Board of Directors makes all precedent setting decisions.
- 6.30 Accreditation Goal
- 6.30.1 Upon accreditation, the organization receives an accreditation certificate listing the applicable accreditation goal. Refer to *Review of Accreditation Applications and Annual Reports, 6.6.002*.
  - 6.30.2 In the case of new FACT accreditation goals or add-on services, accredited organizations remain accredited under the original accreditation goals until specifically inspected and accredited for new services.

### 6.31 Disclosure of Inspection Findings

6.31.1 The inspection findings and current accreditation status prior to FACT accreditation are confidential and are not provided by FACT to third parties with the following exceptions:

6.31.1.1 If an organization is inspected by FACT under contract for a third party, that third party may receive inspection reports (e.g., HRSA Cord Blood Banks).

6.31.1.2 An organization may release its own report at its sole discretion.

6.31.2 Each organization that is currently accredited by FACT is listed on the FACT website: [www.factwebsite.org](http://www.factwebsite.org).

### Appeals Process – Accreditation Outcomes

#### 6.32 Right to appeal

6.32.1 An organization given accreditation pending additional written documentation may not appeal that outcome.

6.32.2 An organization may appeal any interpretation of a citation, but may not appeal the need to comply with a Standard.

6.32.3 If accreditation is not awarded, the organization may send a written statement to the Accreditation Committee Chair outlining reasons the organization disagrees with the inspection team's determination of any citation or variance. If the organization believes that deficiencies or variances were cited in error, an explanation must be included.

6.32.4 An organization that has been required to undergo a reinspection following the on-site inspection and Accreditation Committee review is entitled to one appeal of that determination, provided a written request for reconsideration is received by the FACT Office within 30 days after the organization receives written notice of the accreditation outcome. The written request must provide complete details of the reasons for appeal including all supporting documentation.

#### 6.33 Accreditation Committee Review

6.33.1 Upon receipt of a written appeal of the accreditation outcome, the FACT Accreditation Coordinator will compile the following data for the Accreditation Committee:

6.33.1.1 The original cover letter and report to the organization detailing the outcome of the on-site inspection.

6.33.1.2 The written request for appeal that details the organization's reasons for appeal.

6.33.2 The Accreditation Committee reconsiders the original determination of accreditation status by review of the appropriate documents. The Committee consideration of the appeal must occur within 60 calendar days of receipt of the written appeal request.

6.33.2.1 The Accreditation Committee must decide whether its original determination should stand and the organization is notified in writing of its decision.

6.33.2.2 This decision may be appealed one to the FACT Board of Directors.

## 7.0 Revision History

Date	Revision #	Author/Requestor	Changes	Justification
02May2008	0	Medical Director	New Document	New Document
05Dec2008	1	FACT Staff	<ol style="list-style-type: none"> <li>1. Adjust renewal application delivery to 12 months.</li> <li>2. Change Annual Report to Interim Report</li> </ol>	<ol style="list-style-type: none"> <li>1. Allows organizations an additional three months to complete renewal accreditation process.</li> <li>2. Interim reports allow s accreditation timeline to be more efficient for organizations and FACT.</li> </ol>
23Jan2009	2	Medical Director	<ol style="list-style-type: none"> <li>1. Include requirements for marrow collection facilities without sufficient marrow collection volume.</li> </ol>	<ol style="list-style-type: none"> <li>1. Requirements for this specific situation need to be explicitly stated.</li> </ol>
03Apr2009	3	Medical Director	<ol style="list-style-type: none"> <li>1. Add additional details regarding determination of inspected collection sites for cord blood banks.</li> </ol>	<ol style="list-style-type: none"> <li>1. A variety of collection sites should be inspected for cord blood bank accreditation to ensure standards are followed regardless of collection criteria.</li> </ol>
29May2009	4	Medical Director	Add language describing how inspections should be conducted if inspectors are required to inspect locations prohibiting interaction with the inspection team.	Allows for the inspectors to discuss deficiencies cited from separate locations with the rest of the inspection team.
23Feb2010	5	Board of Directors	<ol style="list-style-type: none"> <li>1. Clarify what a 'focused reinspection' encompasses.</li> <li>2. Include information regarding which Standards edition will be used for 'focused reinspection'.</li> <li>3. Update number of CB Collection Sites inspected vs. total number of collection sites.</li> <li>4. Revise policy on relocation inspection requirements.</li> </ol>	<ol style="list-style-type: none"> <li>1. Previous explanation was unclear.</li> <li>2. Focused reinspection section did not include this necessary information.</li> <li>3. An updated methodology has been approved for the number of collection sites FACT is required to inspect.</li> <li>4. New requirements for organizations submitting documentation to FACT regarding relocation activities approved.</li> </ol>
07Nov2011	6	Board of Directors	<ol style="list-style-type: none"> <li>1. Change title to "Accreditation Process"</li> <li>2. This policy should reflect that contracted collection facilities have two options for accreditation: <ol style="list-style-type: none"> <li>a. Be inspected with each clinical program it serves and only be accredited in relationship to that program</li> <li>b. Pursue independent accreditation when serving multiple clinical programs</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. The new title better reflects the entire accreditation process; not just the inspection portion of the process.</li> <li>2. In order to ensure equitable treatment of all organizations, it is important to clarify policies to allow collection facilities to choose whether they want to be accredited as part of a transplant center's accreditation or to be independently accredited which will afford them the ability to serve multiple programs without being subjected to multiple inspections.</li> </ol>
06Sep2012	7	Director of Operations	<p>The following topics were added to the policy:</p> <ol style="list-style-type: none"> <li>1. Contracted facilities/independent accreditation.</li> <li>2. Accreditation of more than minimal accreditation.</li> <li>3. Accreditation goals.</li> </ol>	Several changes in the organization necessitated these changes, and it was an opportunity to review the process as a whole.

	8	Strategic Planning Administrator	<ol style="list-style-type: none"> <li>1. General updating</li> <li>2. Inspectors shall not be affiliated with an organization located within the same metropolitan statistical area of the applicant organization.</li> <li>3. Describe eligibility of and requirements for accreditation of new services or related clinical services and facilities within the institution.</li> <li>4. Outline requirements for inspection of non-fixed cord blood collection sites.</li> <li>5. Describe requirements of applicants who discontinue cord blood collection or processing activities.</li> <li>6. Specify when suspension or termination could result from reinspections.</li> </ol>	<ol style="list-style-type: none"> <li>1. Make policy consistent with current practice</li> <li>2. Prevent conflicts of interest</li> <li>3. Incorporate new accreditation goals offered by FACT and address contract manufacturing.</li> <li>4. Some non-fixed sites collect often enough to warrant an on-site inspection.</li> <li>5. Clarification.</li> <li>6. Clarification.</li> </ol>
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