

 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER Policies and Procedures</p>	<p>Policy</p>	<p>Document #: ACC.6.1.001 Revision: 9 Approval Date: 10/02/2020 Page 1 of 18 Effective Date: 10/06/2020</p>
<p>Accreditation Process Policy</p>		

1.0 Purpose

This policy establishes guidelines for the FACT accreditation process.

2.0 Scope

This policy applies to FACT personnel, volunteers, and applicant organizations.

3.0 Responsibility

3.1 FACT ensures that:

3.1.1 All FACT personnel, volunteers, and applicant organizations have access to this policy.

3.1.2 This policy is followed.

3.2 Organizations applying for initial or renewal accreditation must follow this policy.

4.0 References

- 4.1 [Clinical Facility Grid](#), ACC.FRM.6.007
- 4.2 [Clinical Outcomes Corrective Action Plan Policy](#), ACC.6.1.007
- 4.3 [Collection Facility Grid](#), ACC.FRM.6.009
- 4.4 [Cord Blood Facility Site Grid](#), ACC.FRM.6.006
- 4.5 [Data Audit Policy](#), ACC.6.1.006
- 4.6 [IEC List](#), ACC.FRM.6.036
- 4.7 [Initial FACT Inspector Qualifications](#), INS.7.1.001
- 4.8 [Inspector Training Program](#), INS.7.2.002
- 4.9 [Maintaining Accreditation](#), ACC.6.1.003
- 4.10 [Processing Facility Grid](#), ACC.FRM.6.010
- 4.11 [Suspension or Termination of Accreditation](#), ACC.6.1.005
- 4.12 [Timelines for Organization Accreditation and Renewal](#), ACC.6.1.008

5.0 Definitions and Abbreviations

- 5.1 **Organization:** Clinical program, cellular therapy collection facility, cellular therapy processing facility, cord blood bank (including cord blood collection sites and cord blood processing facilities), or immune effector cellular therapy program, 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.
- 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 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

Eligibility for Accreditation

- 6.1 An organization must meet certain requirements to be eligible for accreditation.
- 6.2 Clinical Programs must administer a minimum number of cellular therapy products to new patients as required by the applicable Standards.
 - 6.2.1 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.
 - 6.2.2 For HCT autologous accreditation only, a minimum average of five new autologous patients must be transplanted per year within the accreditation cycle.
 - 6.2.3 HCT programs using 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.

- 6.2.4 For immune effector cellular (IEC) therapy accreditation, the program must administer cellular therapy products to a minimum average of five new recipients annually within the accreditation cycle.
- 6.2.5 For accredited HCT programs providing IEC therapy, there is no minimum number of new recipients annually within the accreditation cycle.
- 6.3 A Clinical Program applying for initial FACT accreditation should have passed its most recent CIBMTR Data Audit if one was performed.
 - 6.3.1 If the applicant program failed the most recent Data Audit with a critical field error rate that triggered CIBMTR consequences, the Program must demonstrate significant improvement on an interim CIBMTR audit prior to initial on-site FACT inspection.
 - 6.3.2 If the failing CIBMTR audit did not trigger CIBMTR consequences, the Program may proceed with the accreditation process and on-site inspection.
 - 6.3.3 Refer to [Data Audit Policy](#).

Application for Accreditation

- 6.4 An organization applying for accreditation must complete the process within the timelines defined in the policy [Timelines for Organization Accreditation and Renewal](#).
 - 6.4.1 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.
 - 6.4.2 An organization applying for renewal accreditation must complete the process prior to the expiration of its current accreditation.
- 6.5 An organization applying for initial or renewal accreditation must submit the applicable online application or report.
 - 6.5.1 An organization applying for initial accreditation submits an Eligibility Application and the nonrefundable application fee.
 - 6.5.2 An organization applying for renewal accreditation submits a Renewal Report.
- 6.6 An organization applying for initial or renewal accreditation must meet requirements in accordance with [Clinical Outcomes Corrective Action Plan Policy](#), and [Data Audit Policy](#).
- 6.7 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 Application and Annual Report, ACC.6.6.002*.
 - 6.7.1 An ineligible organization may be eligible to receive a partial application fee refund.
 - 6.7.2 Refer to the FACT Accreditation Fees page for all accreditation fees: http://www.factwebsite.org/Accreditation_Process/Fees.aspx.

- 6.7.3 An organization applying for initial accreditation under the Common Standards must be presented to the Board of Directors to determine eligibility.
- 6.8 The Accreditation Committee Chair or designee may determine that an organization is ineligible for accreditation.
 - 6.8.1 If determined to be ineligible, the organization will be informed in writing, including an explanation of ineligibility.
 - 6.8.2 If the organization disagrees with this decision, the decision may be appealed in writing within 30 days or 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 Directors' President or designee.
 - 6.8.3 The applicant organization will be notified of the decision.
 - 6.8.4 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 6.8.5.
 - 6.8.5 There is no right to further appeal if the determination of the organization's ineligibility is based upon any of the following:
 - 6.8.5.1 The application is incomplete.
 - 6.8.5.2 The Director(s) or the organization does not meet the minimum qualification defined in the Standards.
 - 6.8.5.3 The threshold number of procedures has not been performed or the threshold number of cord blood units has not been banked.
- 6.9 If eligible for accreditation or provisional approval, the organization will be sent instructions for the accreditation process.
- 6.10 The applicant completes and submits the Compliance Application and supporting documents.
- 6.11 Based on review by the FACT Accreditation Coordinator, the organization may be required to submit additional or clarifying information.
- 6.12 When the Compliance Application is acceptable, including uploaded documentation, an inspection team will be assigned.

General Inspection Guidelines

- 6.13 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](#) and [Inspector Training Program](#).
 - 6.13.1 The size and complexity of the facility's operations determines the number of inspectors assigned.

- 6.13.2 Inspection team member 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.
- 6.14 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.
- 6.14.1 A reciprocal inspection is one in which an inspector inspects an applicant organization that employs a prior inspector of his or her organization.
- 6.15 The proposed inspection team is approved by the FACT Chief Medical Officer.
- 6.16 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 the proposed inspectors. The FACT Chief Medical Officer will review the objection. If determined to have merit, a new inspector may be assigned.
- 6.17 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 6.29).
- 6.18 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.
- 6.19 The Organization's Director ensures 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.
- 6.19.1 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.
- 6.19.1.1 If no procedures are occurring on the day of the inspection, the organization should demonstrate a mock administration, collection, or processing of a cellular therapy product for the inspection team.
- 6.19.2 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.
- 6.20 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.

- 6.21 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.
- 6.22 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

- 6.23 Inspection of clinical programs.
 - 6.23.1 All cellular therapy services provided by the Clinical Program must be inspected. To facilitate the inspection of an organization's clinical facilities, Clinical Programs are required to complete the [Clinical Facility Grid](#), to provide detailed information on each site.
 - 6.23.2 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.
 - 6.23.2.1 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 services process. Applicable fees apply.
 - 6.23.3 Immune effector or cellular therapies provided in a different clinical service, but in the same institution as the accredited HCT program, are accredited and inspected as follows:
 - 6.23.3.1 If the service has the same Director, QM Program, and SOPs, it will be considered an additional site. Additional site fee applies.
 - 6.23.3.2 The therapy provided by the service will be added to the HCT accreditation in accordance with the add-on service process. Applicable fees will apply.
 - 6.23.3.3 If the service has a different Director or QM Program, it must apply for separate accreditation.
 - 6.23.3.4 FACT Chief Medical Officer will determine accreditation structure for unique situations.
 - 6.23.4 To facilitate the inspection of an organization's immune effector cellular therapies, Clinical Programs are required to complete the [IEC List](#), to provide detailed information on each therapy administered.
 - 6.23.5 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.
- 6.24 Contracted cellular therapy facilities (e.g., collection or processing) have two options for accreditation:

- 6.24.1 Be inspected with each clinical program it serves and only be accredited in relationship to each program(s), or,
 - 6.24.2 Pursue independent accreditation when serving one or more clinical programs.
- 6.25 Inspection of collection facilities.
- 6.25.1 All cell collection services must be inspected. This includes collection of products for use in the accredited clinical program and those collected only for further manufacturing. To facilitate the inspection of an organization's collection facilities, organizations are required to complete the [Collection Facility Grid](#), to provide detailed information on each site.
 - 6.25.2 Inspection of marrow collection facilities associated with an accredited or applicant clinical program.
 - 6.25.2.1 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.
 - 6.25.2.2 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.
 - 6.25.3 Inspection of apheresis collection facilities associated with an accredited or applicant clinical program.
 - 6.25.3.1 Apheresis collection facilities that perform the minimum number of apheresis collections for FACT accreditation are required to meet all apheresis collection standards and be inspected.
 - 6.25.3.2 Apheresis collection facilities that perform apheresis collections but do not perform the minimum number of apheresis collections for FACT accreditation are required to meet all apheresis collections standards and be inspected, though they are not eligible for FACT accreditation.
 - 6.25.3.3 If more than one apheresis collection facility is to be inspected, additional time on-site may be required. Additional days may be included in the on-site inspection.
- 6.26 Inspection of cellular therapy processing facilities performing cellular therapy product processing with more than minimal manipulation.
- 6.26.1 To facilitate the inspection of an organization's processing facilities, organizations are required to complete the [Processing Facility Grid](#), to provide detailed information on each site.
 - 6.26.2 Processing facilities performing cellular therapy processing with both minimal and more than minimal manipulation must be inspected for both of these activities.

- 6.26.3 When inspecting a facility performing more than minimal manipulation, a minimum of an extra half-day will be included in the inspection period to provide enough time to perform the more complex inspection.
- 6.26.4 More than minimal manipulation activities performed in the same facility as minimal manipulation are inspected and accredited together.
- 6.26.5 Activities performed in a different facility, but in the same institution of the accredited facility, are accredited and inspected as follows:
 - 6.26.5.1 If the facility has the same Director, QM Program, and SOPs, it will be considered an additional site. Additional site fee applies.
 - 6.26.5.2 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. Applicable fees apply.
 - 6.26.5.3 If the facility has a different Director or QM Program, it must apply for separate accreditation.
- 6.27 Readiness assessments of organizations performing a clinical trial or administering commercial cellular therapy products if required by sponsor or manufacturer.
 - 6.27.1 Stand-alone immune effector cellular therapy programs that are not participating in clinical trials or have other mechanisms of access to cellular therapy products may request an assessment of readiness to administer products from manufacturers that require FACT accreditation.
 - 6.27.1.1 Requests must be submitted in writing to the FACT Accreditation Office and will be reviewed by the FACT Board of Directors. If eligible, the organization will be required to complete an Eligibility Application.
 - 6.27.2 Readiness assessments follow the same accreditation process described within this policy, including but not limited to timelines, applications, reports, fees, on-site inspection, Accreditation Committee outcome determinations, and correction of deficiencies (refer to 6.33).
 - 6.27.2.1 Inspections include Standards for clinical, collection, and processing as applicable to the organization's activities.
 - 6.27.3 After compliance with the Standards has been documented, with the exception of the minimum number of patients treated, organizations will be granted "provisional approval" (refer to 6.33).
 - 6.27.4 The organization is eligible for accreditation after it has treated the minimum number of patients with immune effector cellular therapy products as required by the Standards.
 - 6.27.4.1 The organization may request an interim accreditation inspection after treating the minimum number of patients or may choose to wait to begin the accreditation process until the second anniversary of the provisional approval.

If an interim accreditation inspection is requested, FACT will follow its process for add-on inspections.

- 6.27.4.2 Accreditation following provisional approval will follow the established accreditation process, including completion of a new Compliance Application, additional on-site inspection, and correction of deficiencies. If compliance is attained, the organization will be accredited.

6.28 Inspection of cord blood sites.

- 6.28.1 Cord Blood Banks requesting accreditation for cord blood banking must meet the Cord Blood Standards at each site.
- 6.28.2 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*](#), to provide detailed information on each site.
- 6.28.3 All transfer sites, processing facilities, and off-site storage facilities are inspected.
- 6.28.4 If more than one fixed collection site exists, FACT will determine the minimum number of fixed collection sites to be inspected based on the total number of fixed collection sites performing services for the bank:
 - 6.28.4.1 Two sites will be inspected for up to five total collection sites.
 - 6.28.4.2 Three sites will be inspected for up to ten total collection sites.
 - 6.28.4.3 Four sites will be inspected for up to 20 total collection sites.
 - 6.28.4.4 Five sites will be inspected for up to 50 total collection sites.
 - 6.28.4.5 Seven sites will be inspected for up to 100 total collection sites.
 - 6.28.4.6 Nine sites will be inspected for up to 150 total collection sites.
 - 6.28.4.7 Ten sites will be inspected for over 150 total collection sites.
- 6.28.5 For non-fixed collection sites, materials (e.g., recruitment, consent training, SOPs); management of supplies, reagents, and collected cord blood units and tissues; the collection process; and quality data are inspected at the Bank.
- 6.28.6 For non-fixed collection sites where hospital staff other than the physician or midwife collector perform any part of the collection process (including consenting, obtaining maternal samples, assisting in the collection, packaging the unit or samples, or transporting or shipping the unit and samples); where collection kits are stored at the site; or the site collects more than 52 units per year:
 - 6.28.6.1 One site will be inspected for up to five total collection sites.
 - 6.28.6.2 Two sites will be inspected for over five total collection sites.

- 6.28.7 For Cord Blood Banks that use both fixed and non-fixed collection sites, the number of inspected sites will be determined for fixed and non-fixed sites independently of each other.
- 6.28.8 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.
 - 6.28.8.1 For Cord Blood Banks with collection sites in more than one country, at least one site per country will be selected for inspection, with two per country preferred if possible within the total required.
- 6.28.9 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.
- 6.28.10 Cord Blood Banks must be inspected and accredited for all types of donation accepted (unrelated or related), even if rarely accepted.
- 6.28.11 Discontinuation of cord blood collection or processing.
 - 6.28.11.1 Cord Blood Banks must notify FACT upon discontinuation of collection or processing activities in accordance with the policy [Maintaining Accreditation](#). Initial accreditation is not awarded unless both collection and processing services are active.
 - 6.28.11.2 Cord Blood Banks must comply with the NetCord-FACT Standards related to interruption of operations at established sites.
 - 6.28.11.3 Upon reinstatement of collection or processing activities, the Cord Blood Bank must notify FACT in accordance with the policy, [Maintaining Accreditation](#).

Review of Inspection Results

- 6.29 Inspector reports are submitted electronically to FACT within two weeks of the completion of the inspection.
- 6.30 Inspection team members should submit their individual reports to the inspection team leader within three days of the inspection for review and compilation.
- 6.31 The FACT Accreditation Coordinators review the submitted inspector reports and prepare an accreditation report for the Accreditation Committee.
- 6.32 Accreditation reports are available to the Accreditation Committee one week prior to the Accreditation Committee meeting.
 - 6.32.1 All Accreditation Committee members are expected to review each report.
 - 6.32.2 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:

- 6.32.2.1 The report is a response that the Accreditation Committee has requested be re-evaluated by the committee.
- 6.32.2.2 The report contains an excessive number of citations (>20) in one area (e.g., either one facility or quality management).
- 6.32.3 The primary reviewer is responsible for:
 - 6.32.3.1 Reviewing the report, previous reports, and additional documentation as appropriate prior to the committee meeting.
 - 6.32.3.2 Requesting additional information from the FACT Accreditation Coordinator as necessary to understand the report fully.
 - 6.32.3.3 Making recommendations to the committee concerning the adequacy of the response or the appropriateness of the citations.
- 6.32.4 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.
- 6.33 The Accreditation Committee reviews the report to determine a recommended accreditation outcome:
 - 6.33.1 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.
 - 6.33.1.1 Initial accreditation is effective on the date of the Accreditation Committee's decision and effective for three years.
 - 6.33.1.2 Renewal accreditation is effective on the three-year anniversary date,
 - 6.33.1.3 Extenuating circumstances may dictate an alternative accreditation date as described below and in the policy [Timelines for Organization Accreditation and Renewal](#).
 - 6.33.2 Accreditation, pending correction of deficiencies and additional documentation.
 - 6.33.2.1 Documentation by the organization of correction of all deficiencies and a satisfactory response to all variances from recommendations is required.
 - 6.33.2.2 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.
 - 6.33.2.3 Time Interval: 60 days or prior to expiration date, whichever is earlier.
 - 6.33.2.4 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.

- 6.33.2.5 The Accreditation Committee Chair determines the adequacy of the response and may award full accreditation without further Accreditation Committee review.
 - 6.33.2.6 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](#).
 - 6.33.2.7 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.
- 6.33.3 Accreditation, pending Accreditation Committee re-evaluation.
- 6.33.3.1 Significant deficiencies were noted at the on-site inspection.
 - 6.33.3.2 Documentation by the organization of correction of all deficiencies and satisfactory response to variances from recommendations is required.
 - 6.33.3.3 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 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.
 - 6.33.3.4 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.
 - 6.33.3.5 The Committee may require reinspection of all or part of an organization or facility based upon the adequacy of responses submitted.
 - 6.33.3.6 Time Internal: 90 days or prior to the expiration date, whichever is earlier.
 - 6.33.3.7 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 [Suspension or Termination of Accreditation](#).
 - 6.33.3.8 For organizations seeking initial accreditation, if the accreditation process takes significantly longer than normal, as determined by the Accreditation Committee, the accreditation period may be shortened to 3 years from the initial on-site inspection date.
- 6.33.4 Partial Focused Reinspection.
- 6.33.4.1 Major and systemic deficiencies were observed at the on-site inspection, primarily involving one or two areas in the organization.

- 6.33.4.2 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.
- 6.33.4.3 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.
- 6.33.4.4 A reinspection fee applies, as determined by FACT.
- 6.33.4.5 The results of the partial focused reinspection are reviewed by the Accreditation Committee, who determines the accreditation status of the organization.
- 6.33.4.6 Time Interval: 90 days to submit complete response and schedule the reinspection. The reinspection must occur within 90 days of submitting the response.
- 6.33.4.7 The organization's FACT accreditation will be suspended or terminated after the expiration date per policy [Suspension or Termination of Accreditation](#).
- 6.33.4.8 In the event 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.
- 6.33.4.9 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.
- 6.33.4.10 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.
- 6.33.4.11 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.

6.33.4.12 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.

6.33.5 Full Focused Reinspection.

6.33.5.1 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.

6.33.5.2 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.

6.33.5.3 A reinspection fee applies, as determined by FACT.

6.33.5.4 The results of the full focused reinspection are reviewed by the Accreditation Committee, who determines the accreditation status of the organization.

6.33.5.5 Time Interval: 90 days to submit complete response and schedule the reinspection. The reinspection must occur within 90 days of submitting the response.

6.33.5.6 The organization's FACT accreditation is suspended or terminated after the expiration date per policy [*Suspension or Termination of Accreditation*](#).

6.33.5.7 In the event 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.

6.33.5.8 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.

6.33.5.9 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.

6.33.5.10 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.

6.33.5.11 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.

6.33.6 Complete Reinspection.

6.33.6.1 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 the policy [Suspension or Termination of Accreditation](#).

6.33.6.2 Eligibility requirements must be met prior to a complete reinspection of the organization. A new Compliance Application is required.

6.33.6.3 In the event a new edition of Standards is published between the time an organization was initially inspected and a required completed reinspection is conducted, the organization is automatically required to undergo the reinspection under the new edition of Standards.

6.33.6.4 A reinspection fee applies, as determined by FACT.

6.33.6.5 Time Interval: 12 months to submit all required documents and schedule the reinspection. The reinspection must occur within 180 days of submitting the response.

6.33.6.6 The results of the complete reinspection are reviewed by the Accreditation Committee, who determine the accreditation status of the organization.

6.33.6.7 Following reinspection and Accreditation Committee review, the organization is responsible for completing the process in the time interval determined by the Accreditation Committee.

6.33.6.8 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.

6.33.6.9 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.

6.33.6.10 The accreditation date is the date of completion of the current accreditation process.

6.33.7 Provisional Approval.

6.33.7.1 The organization is determined to be ready to administer clinical trial or commercial immune effector cellular therapy products from manufacturers

that require FACT accreditation in compliance with the FACT Standards, except the minimum number of patients.

6.33.7.2 Organizations achieving provisional approval are not accredited and will not be included on FACT's official list of accredited organizations.

- Organizations may not advertise provisional approval in the public domain and must limit disclosure to legitimate efforts intended to promote patient access to cellular therapy.

6.33.7.3 Provisional approval is effective for three years beginning on the date of the Accreditation Committee's decision or documentation of correction of all noted deficiencies.

- The organization must administer immune effector cellular therapy products to the minimum number of patients required by the FACT Standards prior to the expiration of its provisional approval.
- The organization is eligible for only one three-year provisional approval.

6.33.7.4 Extenuating circumstances may dictate the ultimate provisional approval effective dates as described within this policy and in the policy, [Timelines for Organization Accreditation and Renewal](#).

6.34 The Accreditation Committee submits accreditation recommendations to the Board of Directors.

6.34.1 If the Accreditation Committee is unable to reach a consensus for a decision, the Board of Directors will make the final determination.

6.34.2 The Board of Directors reviews, approves, or denies the Accreditation Committee recommendations.

6.34.3 The Board of Directors makes all precedent setting decisions.

6.35 Accreditation Goal

6.35.1 Upon accreditation, the organization receives an accreditation certificate listing the applicable accreditation goal. Refer to *Review of Accreditation Applications and Annual Reports*.

6.35.2 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.

6.36 Disclosure of Inspection Findings.

6.36.1 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:

6.36.1.1 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).

- 6.36.2 An organization may release its own report at its sole discretion.
- 6.36.3 Each organization that is currently accredited by FACT is listed on the FACT website: www.factwebsite.org.

Appeals Process – Accreditation Outcomes

- 6.37 Right to appeal.
 - 6.37.1 An organization given accreditation pending additional written documentation may not appeal that outcome.
 - 6.37.2 An organization may appeal any interpretation of a citation but may not appeal the need to comply with a Standard.
 - 6.37.3 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.
 - 6.37.3.1 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.
- 6.38 Accreditation Committee Review.
 - 6.38.1 Upon receipt of a written appeal of the accreditation outcome, the FACT Accreditation Coordinator will compile the following data for the Accreditation Committee:
 - 6.38.1.1 The original cover letter and report to the organization detailing the outcome of the on-site inspection.
 - 6.38.1.2 The written request for appeal that details the organization’s reasons for appeal.
 - 6.38.2 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 requests.
 - 6.38.2.1 The Accreditation committee must decide whether its original determination should stand, and the organization is notified in writing of its decision.
 - 6.38.2.2 This decision may be appealed once to the FACT Board of Directors.

Add-On Services

- 6.39 An organization may request to add on to its accredited services at any point in the accreditation cycle.

- 6.39.1 The organization must notify the FACT Accreditation Coordinator through the FACT Accreditation Portal, complete the applicable Facility Grid, and the [IEC List](#), if applicable.
 - 6.39.2 If the organization has an open compliance application and has not scheduled its inspection, an additional checklist will be added to the existing compliance application. Additional fees may apply.
 - 6.39.3 If the organization has already been inspected or does not have an open compliance application, a new compliance application will be created with the applicable checklist. An additional fee applies.
- 6.40 The organization must follow the accreditation steps above.
- 6.41 After the accreditation process is completed, the organization will receive a letter and accreditation certificated that includes all accredited services.

Approved by (date):

Heather Conway (Quality Manager) (10/02/2020), Linda Miller (Chief Executive Officer) (10/02/2020),
Phyllis Warkentin (Chief Medical Officer) (12/02/2020)