

 <p>FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY</p> <p>Policies and Procedures</p>	<p><b>Policy</b></p>	<p>Document #: ACC.6.1.008 Revision: 12 Approval Date: 03/September/2023 Page 1 of 4 Effective Date: 03/September/2023</p>
<p><b>Timelines for Organization Accreditation and Renewal</b></p>		

## 1.0 Purpose

The purpose of this policy is to define timelines for organizations to complete the FACT accreditation process.

## 2.0 Scope

This policy is applicable to FACT personnel, and individuals and organizations involved in the FACT accreditation process. This policy is intended to allow adequate and reasonable timelines for organizations seeking initial or renewal accreditation, to ensure consistency of the accreditation process among all accreditation applicants, and to base accreditation decisions on current documentation and inspection observations.

## 3.0 Responsibility

3.1 FACT is responsible to ensure that:

3.1.1 All personnel have access to this policy.

3.1.2 The guidelines described herein are followed.

3.2 Accreditation applicants are responsible for completion of the accreditation process within the timelines defined in this policy.

## 4.0 References

4.1 [Accreditation Process Policy](#), ACC.6.1.001

4.2 [FACT Initial Accreditation Timeline](#), ACC.RES.6.001

4.3 [FACT Renewal Accreditation Timeline](#), ACC.RES.6.002

4.4 [Maintaining Accreditation Policy](#), ACC.6.1.003

4.5 [Suspension or Termination of Accreditation](#), ACC.6.1.005

## 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), facility under the Common Standards, or immune effector cellular therapy program, that has achieved or is applying for FACT accreditation.

- 5.2 Suspension of Accreditation: Temporary discontinuation of an Organization's accreditation. If material evidence of noncompliance to FACT Standards or accreditation requirements exists, including, but not limited to, noncompliance with [Accreditation Process Policy](#), [Maintaining Accreditation Policy](#), and/or adherence to [FACT Renewal Accreditation Timeline](#), an organization will not be accredited and will be removed from the website pending resolution within a defined timeframe of all issues. Refer to [Suspension or Termination of Accreditation](#).
- 5.3 Termination of Accreditation: Revocation of an Organization's accreditation. If material evidence of systemic or severe noncompliance to FACT Standards or accreditation requirements exists, including, but not limited to, noncompliance of [Accreditation Process Policy](#); [Maintaining Accreditation Policy](#); and/or adherence to [FACT Renewal Accreditation Timeline](#), an organization's accreditation will be revoked and reapplication and completion of the accreditation process will be required to regain accreditation. Refer to [Suspension or Termination of Accreditation](#).

## 6.0 Policy

- 6.1 For organizations seeking initial or renewal accreditation, the following timelines are observed:
- 6.1.1 An organization has defined timeframes from application submission to completion of the FACT accreditation process. Refer to [Accreditation Process Policy](#), [FACT Initial Accreditation Timeline](#), and [FACT Renewal Accreditation Timeline](#).
- 6.1.1.1 Each phase of the accreditation process must be completed per the above referenced timelines.
- 6.1.1.2 Each phase in the accreditation process may include multiple steps: submission of all required information, FACT review of the information, and adequate responses to additional request for information. A phase is not complete until each step has been completed.
- 6.1.2 An organization seeking initial FACT accreditation must complete the accreditation process within the established timeline to avoid a shortened accreditation cycle or termination of the accreditation process, as appropriate.
- 6.1.3 An organization seeking renewal of FACT accreditation must achieve renewal accreditation before the expiration date of its most recent accreditation or risk suspension or termination of accreditation in accordance with the policy, [Suspension or Termination of Accreditation](#).
- 6.1.4 An organization that has undergone a significant change involving relocation, addition of services, change in contractual service providers, organizational restructuring, or other changes sufficient to require an interim inspection visit in accordance with policy, [Maintaining Accreditation Policy](#), must complete the process within twelve months of the change.
- 6.1.5 If a new edition of the Standards is published prior to completion of the accreditation process, the inspection will occur under the edition of Standards effective at the time of inspection; this may require the submission of a new application. Applications will not be accepted in the three months period prior to publication of a new edition of Standards.

## 6.2 Enforcement of Initial Accreditation Timeline

- 6.2.1 All new accreditation applicants receive a copy of the appropriate accreditation timeline upon approval of their Eligibility Applications.
- 6.2.2 Organizations that have not completed a phase of the accreditation process based on the timeline will be notified. This notification identifies which phase of the timeline the organization has reached, the maximum allowable time period to respond or take action to continue the accreditation process, and the consequence if the organization does not respond within the applicable time period. The schedule for subsequent phases will be shortened accordingly.
- 6.2.3 If the accreditation process is completed in an amount of time significantly greater than normal, the Accreditation Committee may reduce the period of accreditation to three years from the date of the initial on-site inspection.

## 6.3 Enforcement of Renewal Accreditation Timeline

- 6.3.1 All renewal accreditation applicants receive a copy of the appropriate renewal timeline upon notification of the Renewal Application due date.
- 6.3.2 Organizations that have exceeded a phase of the schedule based on the timeline will be notified. This notification identifies which phase of the timeline the organization has reached, the maximum allowable time period to respond or take action to continue the renewal accreditation process, and the consequence if the organization does not respond within the applicable time period. Subsequent phases will be shortened accordingly.
- 6.3.3 Organizations actively progressing through the accreditation process that have completed their inspections prior to expiration may be given a grace period of up to three months after the date of accreditation expiration to complete their renewal process. During this time, organizations are considered fully accredited and are listed on the FACT website.
  - 6.3.3.1 Organizations requiring a reinspection are not eligible for a grace period.
  - 6.3.3.2 If the renewal process is not completed by the end of the grace period, the organization will be suspended and removed from the FACT website.
  - 6.3.3.3 Failure to meet the requirements of suspension within the timeframe designated will result in termination in accordance with the policy, [Suspension or Termination of Accreditation](#).
- 6.3.4 Adjustments to Accreditation Date
  - 6.3.4.1 The organization's awarded date of accreditation will not fluctuate between accreditation cycles except under unusual circumstances.
  - 6.3.4.2 If a renewal accreditation applicant completes the accreditation process prior to the current accreditation expiration date, the next accreditation expiration date will remain three years from the current date of expiration.

- 6.3.4.3 If a renewal applicant is granted a grace period or requires a partial reinspection, the next accreditation expiration date will remain three years from the current date of expiration.
- 6.3.4.4 If a renewal accreditation applicant is suspended due to the requirement for a complete reinspection of the organization and completes the accreditation process within a 12-month timeframe, the next accreditation date may be awarded based on the day the accreditation process is completed.

#### 6.4 Extenuating Circumstances for Renewal Timeline Extensions

- 6.4.1 Organizations may request an extension of the maximum allowable time periods for the following circumstances:
  - 6.4.1.1 In the event of the death and/or critical illness of the Bank or Program Director, an extension of up to six months to start the renewal process will be granted to the organization. At the end of the extension period, the organization will be expected to begin the renewal accreditation process, and the inspection must be scheduled to occur within six months of starting the renewal process. The accreditation expiration date will remain three years from the current expiration date.
  - 6.4.1.2 In the event of a natural disaster or catastrophic incident (tornado, flood, hurricane, fire explosion, etc.) that causes damage to the physical structure(s) where accredited activities are performed, accreditation will be extended for a period up to six months following resumption of services. Further allowances and/or determinations regarding continuation of accreditation may be made on a case-by-case basis at the request of the organization to the FACT Accreditation Committee Chair or the FACT Board. At the end of the extension period, the organization will be expected to begin the renewal accreditation process, and must schedule the on-site inspection to occur within six months of starting the renewal process. The accreditation expiration date will remain three years from the current expiration date.
- 6.4.2 FACT may proactively grant an extension of no more than three months for factors outside of the organization's control, including but not limited to:
  - 6.4.2.1 The unavailability of inspectors during the allowable time period for inspections.
  - 6.4.2.2 Unusual delays in the accreditation process.
- 6.4.3 Extensions greater than three months require approval of the Chair of the Accreditation Committee or designee.

**Approved by (date):**

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