Provisional Accreditation Policy

1.0 Purpose

This policy establishes guidelines for the FACT provisional 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 provisional accreditation must follow this policy.

4.0 References

4.1 Accreditation Process Policy, ACC.6.1.001

4.2 Timelines for Organization Accreditation and Renewal, ACC.6.1.008

5.0 Definitions and Abbreviations

5.1 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.

5.2 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 Organization**:** Clinical program, cellular therapy collection facility, cellular therapy processing facility, or immune effector cellular therapy program, that has achieved or is applying for FACT accreditation.

5.4 Provisional Accreditation: An optional process wherein a Clinical Program demonstrates compliance with all applicable Standards except those related to patient numbers, and length of Attending Physician experience.

6.0 Accreditation Process

Eligibility Requirements for Provisional Accreditation

6.1 All Organizations

6.1.1 Organizations seeking Provisional Accreditation must comply with all requirements of the *Accreditation Process Policy* except as otherwise provided in this policy.

6.1.2 The organization must not hold any current FACT accreditation in the area (clinical, collection, processing) for which Provisional Accreditation is being sought.

6.1.3 Requests to pursue Provisional Accreditation must be submitted in writing to FACT Headquarters. If eligible, the organization will be required to complete an Eligibility Application.

6.2 Clinical Programs

6.2.1 Programs seeking accreditation for allogeneic transplantation are not eligible for Provisional Accreditation.

6.2.2 Must perform or be operationally ready to perform autologous transplants and/or immune effector cell therapy for adults and/or pediatric patients as appropriate for type of accreditation sought.

6.2.2.1 Must not have met the minimum patient volume required by the applicable Standards.

6.2.3 Physicians responsible for treating patients do not need to meet a minimum cell therapy experience requirement but must be knowledgeable and have documentable training or experience.

6.2.4 Must use products collected and processed in facilities that meet the applicable FACT Standards. Collection and processing facilities must either:

6.2.4.1 Hold current FACT accreditation for the applicable activities; or

6.2.4.2 Be included in and inspected as part of the Clinical Program's application for Provisional Accreditation.

6.3 Collection Facility

6.3.1 Seeking accreditation as part of the Clinical Program's application.

6.3.2 Must use a processing facility that meets the applicable FACT Standards. The processing facility must either:

6.3.2.1 Hold current FACT accreditation for the applicable activities; or

6.3.2.2 Be included in and inspected as part of the Clinical Program's application for Provisional Accreditation.

6.4 Processing Facility

6.4.1 Seeking accreditation as part of the Clinical Program's application.

General Guidelines

6.5 The inspection shall encompass the entire applicable Standards checklist. Organizations are expected to demonstrate compliance with all applicable Standards through implementation of required policies, standard operating procedures, training, quality management systems, and operational processes.

6.6 Where evidence of compliance is contingent upon patient treatment or product administration, programs that have not yet performed these activities will be evaluated based on their documented readiness and implementation of the applicable requirements.

6.6.1 Programs that have completed some, but not the required number, of patient therapeutic events are expected to have all standards implemented.

6.7 After compliance with the Standards has been documented, with the exception of the minimum number of patients treated and related Standards' requirements, organizations will be granted Provisional Accreditation.

6.8 Provisional Accreditation is valid for three years beginning on the date of the Accreditation Committee's determination of full compliance or satisfactory documentation of correction of all noted deficiencies.

6.8.1 The organization is eligible for only one three-year Provisional Accreditation.

6.9 The organization is eligible for full accreditation after it has treated the minimum number of patients for autologous transplant or with immune effector cellular therapy products as required by the Standards.

6.9.1 The organization may request an inspection for full accreditation after treating the minimum number of patients and at least six months have passed after achieving Provisional Accreditation or may choose to wait to begin the accreditation process until the second anniversary of the Provisional Accreditation.

6.9.2 Accreditation following Provisional Accreditation will follow the established accreditation process, including completion of a new Compliance Application, additional on-site inspection, and correction of deficiencies. Upon attaining compliance, the organization will be accredited.

6.10 Organizations achieving Provisional Accreditation will be included on FACT's list of provisionally accredited organizations on the FACT website.

6.10.1 Extenuating circumstances may be considered when determining the Provisional Accreditation effective dates as described within this policy and in the policy *Timelines for Organization Accreditation and Renewal*.

Approved by (date):
Heather Conway (Director, Quality Improvement & Compliance) (17/August/2026), Phyllis Warkentin (Chief Medical Officer) (14/August/2026), Suzanne Birnley (Senior Director, Accreditation Operations) (13/August/2026)