Establishing and Reviewing Standards Policy

1.0 Purpose

The purpose of this policy is to describe the process for establishing, reviewing, and revising FACT Standards. The publication of the Standards is staggered, with each Standards set revised, and a new edition published every three years. Accreditation Manuals that provide guidance information regarding the Standards are revised and published in conjunction with each edition of the Standards. Interim Standards and updated guidance are published when necessary.

2.0 Scope

This policy applies to personnel at FACT or JACIE and to appointed committee members or other volunteers responsible for establishing, reviewing, or revising FACT Standards.

The establishment and review of Standards is conducted by the FACT Standards Committee. The organizational structure of this committee is described below. Refer to the *Standards Committee Organizational Chart* for details.

3.0 Responsibility

3.1 It is the responsibility of FACT to ensure that:

3.1.1 All personnel, committee members, and other volunteers have access to this policy.

3.1.2 The guidelines described herein are followed.

3.2 It is the responsibility of all committee members to complete the FACT Conflict of Interest & Acknowledgments documentation annually or when requested.

4.0 References

4.1 FACT Standards and Accreditation Manuals, including:

4.1.1 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration

4.1.2 FACT-JACIE Hematopoietic Cellular Therapy Accreditation Manual

4.1.3 NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration

4.1.4 NetCord-FACT Cord Blood Accreditation Manual

4.1.5 FACT Common Standards for Cellular Therapies

4.1.6 FACT Common Standards Accreditation Manual

4.1.7 FACT-JACIE Standards for Immune Effector Cells

4.1.8 FACT-JACIE Immune Effector Cells Accreditation Manual

4.2 Standards Committee Organizational Chart, STS.CHT.5.001

4.3 FACT Conflict of Interest & Acknowledgements, CMP.FRM.15.001

5.0 Definitions and Abbreviations

5.1 ASFA: American Society for Apheresis

5.2 ASTCT: American Society for Transplantation and Cellular Therapy

5.3 CBA: Cord Blood Association

5.4 EBMT: Organization formerly known as the European Society for Blood and Marrow Transplantation

5.5 ISCT: International Society for Cell & Gene Therapy

5.6 JACIE: Joint Assurance Committee of ISCT and EBMT

5.7 NetCord: A former global network of non-profit public cord blood banks

5.8 NMDP: National Marrow Donor Program

5.9 WMDA: World Marrow Donor Association

6.0 Policy

6.1 Timeline

6.1.1 The publication of Standards is staggered, with each Standards set revised and a new edition published every three years.

6.1.2 To maintain consistency between the Standards for Immune Effector Cells and the Standards for Hematopoietic Cellular Therapy, these sets of Standards and their respective accreditation manuals are developed and approved concurrently. Following final approval of new editions by the FACT Board of Directors, and, as applicable, the JACIE Executive Committee, the Standards for Hematopoietic Cellular Therapy and the Standards for Immune Effector Cells are published consecutively.

6.2 Standards Committee Membership

6.2.1 FACT Standards Committee Chair

6.2.1.1 The standards development process is led by the FACT Standards Committee Chair, who is appointed by the FACT Board of Directors and who is a member of the FACT Board of Directors and the Executive Committee during their tenure as Chair.

6.2.1.2 The Chair is responsible for:

- Appointing the Standards Subcommittee Co-Chairs, preferably persons who have previously participated as a Standards Committee member.
- In consultation with the FACT Board of Directors, evaluating the need for global changes (e.g., structural reorganization, expansion of scope).
- Leading the general conduct of the Steering Committees.
- Reviewing the activities of the subcommittees and, as desired or requested, participating in subcommittee meetings.

6.2.2 Standards Committee Vice Chairs

6.2.2.1 Two Vice-Chairs are selected for each set of Standards. For jointly published Standards, the FACT Senior Medical Officer or designee serves as one Vice-Chair, and the other organization (e.g., JACIE) appoints one Vice-Chair, preferably that organization's Medical Director.

6.2.2.2 Vice-Chairs are responsible for:

- Overseeing the activities of the subcommittees.
- Participating in the Steering Committee.
- Participating in the review and approval of the revised Standards and Accreditation Manual in conjunction with the subcommittees and Steering Committee.

6.2.3 FACT Standards Development Manager (ex officio, non-voting) is responsible for:

6.2.3.1 Providing professional administrative support to the Standards development process, serving as a liaison to and among the subcommittees, and providing reference materials to the committees as appropriate.

6.2.3.2 Contributing expertise to committee deliberations.

6.2.3.3 Serving as a liaison between the FACT Standards Committees and FACT Accreditation Committees to incorporate the recommendations of each committee into the activities of the other.

6.2.3.4 Incorporating revisions into the Standards and Accreditation Manuals in accordance with established timelines.

6.2.3.5 Preparing the explanations for the rationale for acceptance, revision, or rejection of public comments.

6.2.3.6 Coordinating updates to supplemental and related documents to facilitate the transition to new editions in support of the accreditation process.

6.3 FACT Standards Subcommittees

6.3.1 Subcommittees may be appointed to revise and draft each new edition of the individual sets of Standards.

6.3.1.1 Subcommittee members are volunteers recruited from the membership of ASTCT and ISCT; as appropriate the membership of JACIE parent organizations (ISCT and EBMT), ASFA, CBA, NMDP, and WMDA; and subject matter experts in relevant specialties. Subcommittee members should be affiliated with a FACT- or JACIE-accredited organization.

6.3.1.2 Active FACT inspectors receive priority consideration for committee membership.

6.3.1.3 An attempt is made to include all individuals who volunteer to participate as committee members, as expert reviewers, or in another role as needed. Individuals not selected for a specific role are encouraged to participate in the Standards development process by submitting feedback to the FACT Standards Development Manager at any time or to the Standards Committee via the public review and comment process.

6.3.1.4 The FACT Standards Subcommittees are responsible for:

- Revising Standards and Accreditation Manuals to incorporate scientific, regulatory, and operational developments in cellular therapy; clarify requirements; and implement global changes requested by the FACT Board of Directors, the JACIE Committee, or Standards Committee Chair.
- Maintaining harmonization among different sets of FACT Standards when appropriate.
- Evaluating and addressing feedback submitted to FACT or JACIE since the previous edition was published.
- Reviewing comments submitted during the public review and comment period and making edits as appropriate.

6.3.2 FACT Standards Steering Committee

6.3.2.1 The Steering Committee is comprised of the Standards Committee Chair, Vice-Chairs, Past Chair(s), Co-Chairs of each subcommittee, and the FACT Standards Development Manager.

6.3.2.2 The Steering Committee is responsible for:

- Coordinating the subcommittee activities to ensure consistency in standard setting among subcommittees.
- Reviewing and resolving undecided or controversial issues that have arisen within the subcommittees.

- Approving draft Standards and Accreditation Manuals for submission to the FACT Board of Directors, and if applicable, the JACIE Committee, for final review and approval prior to publication for public comment and prior to final publication.

- Approving the explanations prepared for the rationale for acceptance, revision, or rejection of public comments.

6.4 Committee Meeting Conduct

6.4.1 A quorum (simple majority) must be present before the meeting may be called to order. In the absence of quorum, no final motions or decisions will be made.

6.4.2 In general, decisions are made by consensus. Unresolved issues are referred to the Steering Committee or the FACT Board of Directors and, if applicable, the JACIE Committee leadership.

6.5 Creation of New Editions of Standards and Accreditation Manuals.

6.5.1 Preparation of Drafts.

6.5.1.1 Subcommittees draft their respective sections of the Standards and the related guidance information in the Accreditation Manual.

6.5.1.2 The Steering Committee reviews the progress of the subcommittee activities and resolves controversial issues on an ongoing basis.

6.5.1.3 After completion of the first draft of the Standards, the Steering Committee performs a comprehensive review of the draft, incorporates necessary edits, and approves the resulting draft for submission to the FACT Board of Directors, the JACIE Committee (if applicable), and legal counsel.

6.5.1.4 Feedback from the FACT Board of Directors, the JACIE Committee (if applicable), and legal counsel is reviewed by the Standards Committee Chair, Vice-Chairs, and Standards Development Manager. Significant observations are discussed by the Steering Committee.

6.5.2 Publication of Drafts for Public Review and Comment.

6.5.2.1 With approval from the FACT Board of Directors and, if applicable, the JACIE Committee, the draft Standards, and, if desired, the Accreditation Manual, are published for 60-90 days for public comment.

6.5.2.2 When requested by the Standards Committee, a second 30-day public comment period may be required.

6.5.2.3 Interim Standards or revised Standards developed due to the urgency of an issue may be published for a 30-day public comment period.

6.5.2.4 Input is specifically requested from regulatory bodies and stakeholder organizations as applicable.

6.5.2.5 Each submitted comment is reviewed by the Standards Committee and, as appropriate, relevant edits are made.

6.5.2.6 Comments submitted via the public comment process are tracked for review by the Standards Committee. Comments and committee rationale are published concurrently with the Standards and Accreditation Manual.

6.5.2.7 The resulting final drafts of the Standards and the Accreditation Manual are submitted to the FACT Board of Directors, the JACIE Committee (if applicable), and legal counsel.

6.5.2.8 Feedback is reviewed as described in 6.5.1.4, and final approval for publication is obtained from the FACT Board of Directors and, as applicable, the JACIE Committee.

6.5.3 Transition to New Edition of Standards and Accreditation Manual.

6.5.3.1 The effective date of a new edition of Standards is a minimum of 90 days after publication.

6.5.3.2 Applications for accreditation using the previous edition of Standards and related documents are not accepted on or after the publication date of a new edition.

6.5.3.3 Inspections using the previous edition are not scheduled on or after the effective date of the new edition.

6.5.3.4 Extenuating factors may require adjustment of the transition timeline.

6.6 Ongoing Feedback

6.6.1 Feedback from the public regarding the Standards or Accreditation Manual may be submitted to FACT at any time.

6.6.2 The Standards Committee Chair, the FACT Senior Medical Officer, and the Standards Development Manager determine if the feedback should be further assessed for a potential interim standard or considered for the next Standards edition.

6.6.3 Revised versions of the Accreditation Manual may be published periodically if the revisions do not change the intent or interpretation of the Standards.

6.7 Interim Standards

6.7.1 In the event of urgent issues related to patient safety or Applicable Law, interim standards may be necessary.

6.7.2 Proposed interim standards and applicable guidance information are drafted, reviewed, and approved by the Standards Steering Committee and submitted for legal review.

6.7.3 The FACT Board of Directors, and, as applicable, the JACIE Committee, approve the proposed interim standard and applicable guidance information.

6.7.4 Interim standards may be published for public review and comment if necessary.

6.7.5 Interim standards are effective 30 days after publication.

Approved by (date):
Heather Conway (Quality Manager) (01/May/2025), Yossi Schwartz (23/April/2025)