


|                                                                                                                                                                                                                                    |                      |                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------|
|  <p>FOUNDATION FOR THE<br/>ACCREDITATION OF<br/>CELLULAR THERAPY<br/>AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER<br/>Policies and Procedures</p> | <p><b>Policy</b></p> | <p>Document #: 5.1.001<br/>Revision: 10<br/>Valid Date: 14Mar2019<br/>Page 1 of 7<br/>Effective Date: 14Mar2019</p> |
| <p><b>Establishing and Reviewing Standards</b></p>                                                                                                                                                                                 |                      |                                                                                                                     |

## 1.0 Purpose

The purpose of this document is to detail the policy for establishing and reviewing the FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration, Common Standards for Cellular therapies, and Standards for Immune Effector Cells, all referred to henceforth as ‘the Standards’ unless otherwise specified.

This policy is to be used by volunteers and personnel involved in the generation and review of the Standards provided by FACT in collaboration with other entities.

## 2.0 Scope

This procedure is applicable to personnel at FACT, as well as JACIE, NetCord, affiliated agencies as appropriate, and other appointed committee members responsible for establishing, reviewing, implementing, and revising these Standards.

The publication of the Standards are staggered, with each document revised and a new edition published every three years.

The establishment and review of Standards is conducted within the FACT Standards Committee. The organizational structure of this committee is described below. The Standards Committee Organizational Chart is detailed in 5.1.001 Form 1.

## 3.0 Responsibility

3.1 It will be the responsibility of FACT to ensure that:

- 3.1.1 All FACT Directors, personnel, committee members, and inspectors have access to this SOP.
- 3.1.2 The guidelines described herein are followed.
- 3.1.3 The organizational structure and applicable chain of command is followed.

|                                                                                     |                                                                                      |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <p><b>Document Approvals</b></p>                                                    |                                                                                      |
|  |  |
| <p><b>Linda Miller</b><br/>Chief Executive Officer</p>                              | <p><b>Heather J. Conway</b><br/>Quality Manager</p>                                  |

## 4.0 References

- 4.1 FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration
- 4.2 NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration
- 4.3 Common Standards for Cellular Therapies
- 4.4 Standards for Immune Effector Cells
- 4.5 FACT Standards Committee Organizational Chart, 5.1.001 Form 1
- 4.6 Conflict of Interest Policy, CON.2.1.001
- 4.7 Confidentiality Policy, CON.2.1.002
- 4.8 FACT Annual Compliance, CON.FRM.2.003
- 4.9 FACT Bylaws, 3.1.001

## 5.0 Definitions

- 5.1 ASBMT: American Society for Blood and Marrow Transplantation
- 5.2 EBMT: European Group for Blood and Marrow Transplantation
- 5.3 ISCT: International Society for Cellular Therapy
- 5.4 JACIE: Joint Accreditation Committee of ISCT and EBMT
- 5.5 NetCord: A global network of non-profit public cord blood banks
- 5.6 NMDP: National Marrow Donor Program
- 5.7 WMDA: World Marrow Donor Association

## 6.0 Policy

- 6.1 FACT Standards Chair
  - 6.1.1 Selection
    - 6.1.1.1 The Standards Chair will be appointed by the FACT Board of Directors and other participating organizations (e.g., JACIE, NetCord) will be notified as appropriate.
    - 6.1.1.2 The Standards Chair will serve an approximately three-year term concomitant with one edition of each set of Standards.
    - 6.1.1.3 The Standards Chair may be reappointed for additional terms as defined in the Bylaws.
  - 6.1.2 Function
    - 6.1.2.1 The Standards Chair is responsible for:
      - 6.1.2.1.1 Creating and distributing meeting agendas to Steering Committee members.
      - 6.1.2.1.2 Leading the general conduct of the Steering Committee meeting.
      - 6.1.2.1.3 Reviewing agendas, minutes, and draft Standards and Guidance from subcommittee meetings.
      - 6.1.2.1.4 Participating in subcommittee meetings as desired and/or requested.
    - 6.1.2.2 The Standards Chair is a member of the:
      - 6.1.2.2.1 FACT Board of Directors.
      - 6.1.2.2.2 Executive Committee of the FACT Board.

## 6.2 FACT Standards Committee Co-Chairs

### 6.2.1 Selection

- 6.2.1.1 Two co-chairs will be selected for each set of Standards.
- 6.2.1.2 The FACT Board of Directors will appoint a co-chair for each of the Standards.
- 6.2.1.3 JACIE will appoint a co-chair for the Cellular Therapy Standards.
- 6.2.1.4 NetCord will appoint a co-chair for the Cord Blood Standards.

### 6.2.2 Function

- 6.2.2.1 Oversee the activities of the subcommittees.
- 6.2.2.2 Review and approve revised standards and guidance information prior to drafts of the Standards and Accreditation Manual being forwarded to the Standards Committee Chair. The approval of the revised Standards and Accreditation Manual should be performed by the subcommittees and/or Steering Committee.
- 6.2.2.3 Participate in interim standards and guidance writing and approval.

## 6.3 FACT Standards Development Manager

### 6.3.1 Selection

- 6.3.1.1 The FACT office representative is the Standards Development Manager or designee.
- 6.3.1.2 Other FACT office personnel may participate in the Standards development process.

### 6.3.2 Function

- 6.3.2.1 Work with (sub)committees and coordinate their meetings to outline and compile the Standards and Accreditation Manual.
- 6.3.2.2 Contribute expertise to committee deliberations.
- 6.3.2.3 Provide reference material to committee, such as published articles and reference documents.
- 6.3.2.4 Ensure that the Standards and Accreditation Manual are edited appropriately and are ready for publication in the timeframe determined by the FACT Board of Directors.
- 6.3.2.5 Prepare additional references, such as crosswalks.
- 6.3.2.6 Coordinate the updating or institution of supplemental documents and online forms used to facilitate the inspection and accreditation process.
- 6.3.2.7 Coordinate the process of developing interim standards.
- 6.3.2.8 Assist committees with administrative functions, such as meeting minutes, edits and revisions, etc.
- 6.3.2.9 Serve as a liaison between the Standards Committee and the Accreditation Committee, and ensure decisions from each committee are incorporated into the activities of the other.
- 6.3.2.10 Develop training programs for current editions of Standards and Guidance.

## 6.4 FACT Standards Subcommittees

### 6.4.1 Selection

- 6.4.1.1 Subcommittees will be appointed to revise and draft each new edition of FACT-JACIE and NetCord-FACT Standards. The subcommittees will be appointed approximately 24-48 months prior to the anticipated release of a new edition of Standards.

- 6.4.2 CTP Standards subcommittees include:
  - 6.4.2.1 CTP Clinical Standards
  - 6.4.2.2 CTP Collection Standards
  - 6.4.2.3 CTP Processing Standards
- 6.4.3 Cord Blood Standards subcommittees include:
  - 6.4.3.1 Cord Blood Quality Management and Operational Standards
  - 6.4.3.2 Cord Blood Donor Management and Collection Standards
  - 6.4.3.3 Cord Blood Processing, Selection, and Release Standards
- 6.4.4 Two co-chairs will be appointed to lead each of the subcommittees.
- 6.4.5 Subcommittee members will be volunteers recruited via an open invitation to the membership of the FACT parent organizations (ASBMT and ISCT), JACIE parent organizations (EBMT and ISCT), and NetCord.
  - 6.4.5.1 Every attempt will be made to include all individuals who desire to participate as committee members, as expert reviewers, or in another role as needed.
  - 6.4.5.2 Exceptions may be made when numerous individuals from the same organization wish to serve on the same subcommittee. In this event, every effort will be made to identify an alternative mechanism for interested individuals to contribute to the FACT mission.
  - 6.4.5.3 When necessary to include additional expertise and/or representatives from other groups, direct invitations to individuals outside the open recruitment may be offered.
  - 6.4.5.4 Five representatives from FACT will be appointed to each applicable CTP subcommittee by the FACT Board of Directors in addition to the subcommittee co-chairs.
  - 6.4.5.5 Five representatives from JACIE will be appointed to each applicable CTP subcommittee by the JACIE Board of Directors in addition to the subcommittee co-chairs.
  - 6.4.5.6 One representative from NMDP and WMDA may be appointed to each applicable subcommittee by their respective organizations.
  - 6.4.5.7 The FACT Board of Directors, JACIE Board of Directors, and NetCord Board of Directors will approve all committee appointments from their respective organizations.
  - 6.4.5.8 The FACT Office staff will notify members of selection, and coordinate compilation of relevant credentials and required documents.
- 6.4.6 Function
  - 6.4.6.1 All subcommittee members must complete *FACT Annual Compliance* (CON.FRM.2.003) prior to participation.
  - 6.4.6.2 All subcommittees will follow the process for standards development as outlined in this document.

## 6.5 Steering Committee

- 6.5.1 Selection
  - 6.5.1.1 The Steering Committees for CTP Standards and CBB Standards will be nominated by the Standards Chair and appointed by the FACT Board of Directors to oversee and coordinate the efforts of the individual subcommittees.

- 6.5.2 The composition of the Steering Committee will include representation from FACT, JACIE, and NetCord, as applicable. The Steering Committee will also include (at a minimum):
  - 6.5.2.1 The chair of the Standards Committee.
  - 6.5.2.2 The chair of the appropriate Accreditation Committee and/or the Medical Directors of FACT and JACIE, as appropriate.
  - 6.5.2.3 The co-chairs of the Standards Committees.
  - 6.5.2.4 The co-chairs of the individual Standards Subcommittees.
  - 6.5.2.5 The FACT Standards Development Manager (non-voting).
- 6.5.3 Function
  - 6.5.3.1 In consultation with the FACT Board of Directors, evaluate the need for global changes in a new edition of Standards (e.g., structural reorganization, addition or deletion of sections, expansion of cell types, facilities to be included, etc.).
  - 6.5.3.2 Define the subcommittee responsibilities and timelines.
  - 6.5.3.3 Coordinate subcommittee actions to ensure consistency in standard setting among the subcommittees.
  - 6.5.3.4 Monitor the progress of the subcommittees to ensure adherence to timelines.
  - 6.5.3.5 Review unresolved and/or controversial issues that arise within the subcommittees for presentation to and final reconciliation by the FACT Board of Directors and the JACIE Board of Directors or NetCord Board of Directors.
  - 6.5.3.6 Prepare the next edition draft for approval from the FACT Board of Directors and JACIE and NetCord as applicable.
  - 6.5.3.7 Receive and review all submitted public comments in conjunction with subcommittees.
  - 6.5.3.8 Revise the draft documents as appropriate and prepare the final drafts for approval by the FACT Board of Directors (and JACIE and NetCord as applicable).
  - 6.5.3.9 Conduct a meeting prior to initiation of subcommittee activities and, at a minimum, monthly thereafter. Additional meetings may be called on an impromptu basis as needed.
  - 6.5.3.10 Generate a crosswalk of existing FACT Standards and any regulatory requirements released in the interim since adoption of the current version of FACT Standards. This will occur prior to initiation of subcommittee activity and may include input from other groups, such as the FACT Professional Relations Committee.

## 6.6 Committee Meeting Structure and Conduct

- 6.6.1 Committee meetings may be held in person, via teleconference, or through web-based meetings.
- 6.6.2 All committee meetings will follow the following procedures:
  - 6.6.2.1 An agenda will be established by the committee chair(s) and distributed to committee members prior to each meeting.
  - 6.6.2.2 The FACT Standards Development Manager will perform a roll call at the beginning of each meeting to document attendance.
  - 6.6.2.3 A quorum (simple majority) must be present before the meeting may be called to order. In the absence of a quorum, no final motions or decisions may be made.

- 6.6.2.4 In the event that two consecutive meetings must be canceled due to lack of a quorum, the Steering Committee must be informed and will be empowered to adjust the subcommittee composition, number, and/or meeting times to prevent further delays.
- 6.6.2.5 In the presence of a simple majority, the meeting will be called to order by the chair and minutes from the previous meeting will be approved.
- 6.6.2.6 The committee chair(s) will lead discussion of the agenda items and will be responsible for the conduct of the meeting.
- 6.6.2.7 The subcommittee will develop, revise, and review related guidance information simultaneously with the standards.
- 6.6.2.8 In general, decisions will be made by consensus.
- 6.6.2.9 Resolution of divided issues will be postponed pending review of relevant literature, when available, and further subcommittee discussion.
- 6.6.2.10 An attempt to reach consensus will be made by a vote among the voting members of the committee. Issues that remain unresolved will be referred to the Steering Committee and FACT Board of Directors, JACIE Board of Directors, and/or NetCord Board of Directors as applicable for resolution.
- 6.6.2.11 All meetings will be adjourned at the agreed upon completion time.
- 6.6.2.12 Minutes of the meeting will be taken by the FACT Standards Development Manager and forwarded to the chair for editing. A final copy of the minutes will be provided to committee members for approval at the next meeting.
- 6.6.2.13 Agenda and minutes for all subcommittee meetings will be provided to the Steering Committee.

## 6.7 Completing Revised Standards and Accreditation Manual

- 6.7.1 Initiate Review Process
  - 6.7.1.1 Steering Committee assigns subcommittee tasks, including the responsibilities for drafting the Standards and Accreditation Manual.
  - 6.7.1.2 Steering Committee discusses potential global changes for the Standards and submits recommendations to FACT, JACIE, and/or NetCord Boards (as applicable) for approval.
  - 6.7.1.3 FACT committee members complete the crosswalk of current Standards and FDA guidelines in conjunction with the Steering Committee and office staff.
  - 6.7.1.4 JACIE Executive Officer completes a crosswalk of current FACT-JACIE Standards and European regulations in conjunction with JACIE representatives on the Standards Committee and Subcommittees.
  - 6.7.1.5 The FACT Standards Development Manager, in conjunction with office staff, organizes and reviews comments and suggestions regarding the existing Standards and/or Accreditation Manual that have accumulated since the last edition. The comments and suggestions are forwarded to the proper subcommittees who incorporate the revisions as appropriate.
- 6.7.2 Create Draft Standards and Accreditation Manual
  - 6.7.2.1 Subcommittees draft their respective new standards and guidance information.
  - 6.7.2.2 Subcommittee chair and co-chairs review standards and guidance information.
  - 6.7.2.3 The FACT Standards Development Manager (or designee) makes suggested revisions and forwards to subcommittee co-chairs.

- 6.7.2.4 Subcommittee co-chairs review standards and guidance.
- 6.7.3 Prepare Draft for Steering Committee Review
  - 6.7.3.1 The FACT Standards Development Manager (or designee) makes suggested revisions and forwards to Standards Chair and Steering Committee.
  - 6.7.3.2 Standards Chair and Steering Committee review draft Standards and Accreditation Manual.
- 6.7.4 Review Draft
  - 6.7.4.1 In-person Steering Committee meeting is conducted to review draft Standards and Accreditation Manual.
  - 6.7.4.2 The FACT Standards Development Manager (or designee) revises draft Standards and Accreditation Manual as directed from the Steering Committee review.
  - 6.7.4.3 Steering Committee approves resulting draft for submission to the Boards of Directors.
- 6.7.5 Obtain Approval of Draft from Boards of Directors to Publish Draft for Public Comment
  - 6.7.5.1 Legal review of resulting draft Standards and Accreditation Manual.
  - 6.7.5.2 FACT Board of Directors, JACIE Board of Directors and/or NetCord (as applicable) review draft Standards and Accreditation Manual.
  - 6.7.5.3 FACT Board of Directors, JACIE Board of Directors and/or NetCord (as applicable) approval of publication for comment.
- 6.7.6 Revise Draft as Requested by Boards of Directors
  - 6.7.6.1 Steering committee revisions subsequent to legal and FACT Board of Directors, JACIE Board of Directors and/or NetCord review.
  - 6.7.6.2 Legal review if substantive changes result.
- 6.7.7 Publish Draft for Public Inspection and Comment
  - 6.7.7.1 Draft Standards and Guidance are published for approximately 90-days for public comment, minimum of 60-days.
  - 6.7.7.2 Urgent issues are published for a minimum of a 30-day public comment period.
- 6.7.8 Review Public Comments
  - 6.7.8.1 Steering committee and subcommittees review comments and make necessary revisions.
  - 6.7.8.2 Steering committee approves final draft for submission to the Boards of Directors.
- 6.7.9 Obtain Approval to Publish Standards and Accreditation Manual
  - 6.7.9.1 Legal review of final draft.
  - 6.7.9.2 FACT Board of Directors, JACIE Board of Directors and/or NetCord (as applicable) approve final draft for publication.
- 6.7.10 Direct FACT staff to prepare and publish Standards, Accreditation Manual, and associated documents and online forms.
  - 6.7.10.1 Effective date will be established at the time of publication. The effective date will be a minimum of 90- days after publication.
- 6.7.11 Checklists from the previous edition of Standards will not be accepted on or after the publication date.
- 6.7.12 Inspections using the previous edition of Standards will not be scheduled on or after the effective date.

## 6.8 Ongoing Feedback

- 6.8.1 Comments from the public regarding the Standards and/or Accreditation Manual may be submitted at any time.
  - 6.8.1.1 Non-urgent comments are compiled and organized by the Standards Development Manager and are presented to the Standards Chair on an ongoing basis.
  - 6.8.1.2 If the Standards Chair determines the comments should be considered for the next Standards edition, he/she will direct the Standards Development Manager to retain the comments for the next Standards development period.
  - 6.8.1.3 If the Standards Chair determines the comments deserve consideration as potential interim standards, he/she distributes the drafted standards to the Standards Committee.
  - 6.8.1.4 The Standards Committee reviews the proposed standards and determines by consensus if the revisions should be submitted to the applicable Boards for approval.
  - 6.8.1.5 If changes are needed to the Accreditation Manual for purposes of clarity, but do not result in changes to or interpretation of the Standards, updated versions of the Accreditation Manual will be published electronically.
  - 6.8.1.6 If the decision is to submit the revised standards to the applicable Boards, steps 6.9.1.3 – 6.9.1.7 shall be followed.

## 6.9 Interim Standards and Accreditation Manual

- 6.9.1 In the event of urgent issues, laws, or regulations, interim standards may be necessary.
  - 6.9.1.1 The FACT Standards Development Manager compiles comments, suggestions, etc. and provides the list to the FACT Board of Directors, JACIE Board of Directors, and/or NetCord, and Standards Chair.
  - 6.9.1.2 When necessary, the Standards Chair calls to order a meeting of the Steering Committee.
  - 6.9.1.3 Proposed standards and/or applicable guidance information are drafted, reviewed, and approved by the Steering Committee.
  - 6.9.1.4 Proposed interim standards and/or applicable guidance information is submitted for rapid legal review.
  - 6.9.1.5 The FACT, JACIE, and/or NetCord Boards of Directors (as applicable) approve the proposed standards and/or applicable guidance information.
  - 6.9.1.6 The FACT, JACIE, and/or NetCord Boards of Directors (as applicable) may choose to publish an interim standard for public comment if necessary.
  - 6.9.1.7 Interim standards and/or applicable guidance information are published and effective within 30 days of publication.



## 7.0 Revision History

| Date      | Revision # | Author/Requestor                             | Changes                                                                                                                                                                                                                                                                                                                                   | Justification                                                                                                                                                                                                                                                                                               |
|-----------|------------|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10Oct2007 | 0          | FACT Board                                   | New Document                                                                                                                                                                                                                                                                                                                              | New Document                                                                                                                                                                                                                                                                                                |
| 18Oct2007 | 1          | FACT Board                                   | Add statement regarding global changes to Standards                                                                                                                                                                                                                                                                                       | Global changes to Standards not specifically addressed in timeline.                                                                                                                                                                                                                                         |
| 07Feb2008 | 2          | FACT Board                                   | 1. Add statement regarding BOD's involvement with global changes to Standards.<br>2. Adjust outline format to have fewer subcategories.                                                                                                                                                                                                   | 1. BOD's involvement in Standards approval process not explicitly stated.<br>2. Maximum of 4 subcategories recommended per document #1.1.001                                                                                                                                                                |
| 05Mar2008 | 3          | FACT Board                                   | 1. Add additional information regarding when and how interim standards may be submitted.<br>2. Adjust general timeline for revising Standards from Months 2-4 to Months 2-5. Future months adjusted accordingly.                                                                                                                          | 1. No information was previously stated how interim standards were to be handled.<br>2. Timeline adjusted to be in compliance with actual practice.                                                                                                                                                         |
| 24Nov2008 | 4          | Standards Committee                          | Revise Cord Blood Organizational Chart                                                                                                                                                                                                                                                                                                    | Names of CB Subcommittees changed to better reflect charges. Co-chairs may be national or international.                                                                                                                                                                                                    |
| 10Feb2009 | 5          | FACT Board/Standards Committee               | 1. Interim revisions of Accreditation Manual will be published electronically.<br>2. Revise Standards Timeline from 12 months to 15 months; sub-sections adjusted accordingly                                                                                                                                                             | 1. Revisions will be made for clarification purposes only; they will not affect the interpretation.<br>2. Revised for continuous improvement of standards setting process efficiency.                                                                                                                       |
| 06Jan2010 | 6          | FACT Board                                   | 1. Change month-by-month process to tasks.<br>2. Change JACIE Executive Committee to JACIE Board of Directors.<br>3. Clarify FACT Standards Chair is nominated at discretion of FACT BOD with notification to applicable organization.<br>4. Change subcommittee appointment time from 18 to 24 months prior to release of the Standards. | 1. Timeline will be adjusted; prevent future revisions of policy when timeline is adjusted for unique issues.<br>2. At request of JACIE; full JACIE Board approves Standards.<br>3. Unclear in current revision.<br>4. Allows for additional time to review and revise Standards.                           |
| 24Jan2011 | 7          | FACT Board/Standards Committee               | Allow Boards of Directors to publish interim standards for public comment if deemed necessary.                                                                                                                                                                                                                                            | This should be an option for the Boards if they deem the revisions would benefit from public comment. The comment period will be at the discretion of the Boards, and not a requirement.                                                                                                                    |
| 22Dec2011 | 8          | Manager, Standards Development and Education | -Update steps that will change with FACTWeb.<br>- Include updated processes related to committee invitations, review of public comments, and meetings without quorum.<br>- Minor improvements in grammar and explanation of some steps.<br>- Update organizational chart.                                                                 | - FACT changed process for reviewing public comments due to implementation of FACTWeb.<br>- Processes were streamlined to provide better efficiency.<br>- Some steps could be described more accurately.<br>- The organizational chart needs to include WMDA and NMDP representatives on all subcommittees. |
| 03Jun2013 | 9          | Director of Operations                       | Updated position titles, generally refreshed language.                                                                                                                                                                                                                                                                                    | New Standards Development Specialist position.                                                                                                                                                                                                                                                              |
| 14Mar2019 | 10         | Chief Medical Officer                        | -added definition to public comment periods with minimums defined<br>- added that standards are effective a minimum of 90 days after publication                                                                                                                                                                                          | Public comment periods may vary depending on the content of the proposed change.<br>Minimum period should be defined.                                                                                                                                                                                       |