FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

Summary of Changes

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

This document summarizes the major changes in the eighth edition *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration* from version 7.0 published in 2019. This summary does not include all changes, minor or verbiage changes, or clarifications that do not alter the intent of the Standards. During this revision, there were intentional efforts to harmonize the *NetCord-FACT Cord Blood Standards* with the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration,* edition 8.1, effective January 2022.

This document is organized into two primary sections and multiple subsections. "Major Changes" and its corresponding table identify concepts present throughout the document that impact all areas of cord blood collection, banking, and release for administration, including a new tenet and new definitions. "Changes by Section" and the immediately following table examine Operational Standards (Part B), including Quality Management, and details changes which impact the function of the bank. The subsequent tables in this section summarize Standards specific to Collection (Part C), Cord Blood Processing (Part D), and the practice of listing, search, selection, reservation, release, and distribution of the cord blood unit (Part E). Finally, major changes to the appendices are noted in the last table.

Each table includes the subject matter of the change, an explanation of its rationale or intention, and its location in the Standards. In the location column, the word "Standards" represents multiple Standards in the specified location which are related to the change.

Major Changes

Topic	Explanation	Related Standard(s)
New tenet: *A2.2*	A new tenet (a basic principle that is true throughout the Standards) has been added to permit flexibility in the delegation of specific activities.	A2.2 The phrase "or designee" was removed from individual Standards throughout.
New concept: *ISBT 128 Coding and Labeling*	Full implementation of the ISBT 128 coding and labeling system, as applicable, is required when the labeling is under the control of the accredited facility.	B6.1, B6.1.1, B6.1.2 Appendix II
New concept: *Accreditation of HLA Typing Laboratories*	The College of American Pathologists (CAP) has been approved as an accrediting organization appropriate to provide histocompatibility services for hematopoietic cellular therapy and is expressly listed in the Standards.	B5.5
Revised definition: *Cellular therapy product*	To define products with the intent of providing effector cells in the treatment of disease or supportive therapy.	A4
Revised definition: *Clinical Program*	Definition clarified to include staffing, operation, quality management, and outcomes requirements.	A4
New definition: *Exceptional release*	New term included to define a product that fails to meet specified criteria for distribution.	A4

Major Changes

Topic	Explanation	Related Standard(s)
New definitions: *Good practices, GMP, GTP, and GxP*	Definitions added to the revised definition of "Good Manufacturing Practice (GMP)" to delineate the good practices that must be followed as applicable to the processes performed by a specific entity for a given cellular therapy and to define related training.	A4
Revised definition: *ISBT 128*	Revised to define a global standard published by ICCBA for the identification, labeling, and information transfer of human blood, cell, and tissue products.	A4
New definition: *Package insert*	New definition added because *the NetCord- FACT Cord Blood Standards* apply to licensed cellular therapy products where the package insert is an extension of the product label that provides important information about the product.	A4
New definition: *Preparative (conditioning) regimen*	New term introduced to define treatments used to prepare a patient for cellular therapy product administration.	A4
New definition: *Qualified person*	New term introduced to define a person who has received training and has documented competence in the task assigned. Tasks can be delegated to a qualified person.	A4
New definition: *Responsible person*	New term introduced to define a person authorized to perform designated functions.	A4

Changes by Section

PART B: OPERATIONAL STANDARDS	
Topic	**Related Standard(s)**
Key personnel responsible for the aspects of Quality Management	B2.1.1, B2.2.1
GxP training requirements	B2.5.4.4
Change control – Additional requirement: Assessment of need to qualify equipment, supplies, or reagents	B2.6.5.1
Change control – Additional requirement: Change in practice shall not occur before a change control plan has been approved for implementation	B2.6.6.1
Description of change when a document is amended	B2.7.4.1
Review of controlled documents listed in B2.7.1 every two (2) years at a minimum	B2.7.7
Archival of obsolete controlled documents	B2.7.9
Note: The section on audits was significantly reorganized and includes multiple new Standards.	B2.11 Standards
Audit reports	B2.11.3 Standards
Approved audit plan as part of audit report	B2.11.3.1
Audit of focused areas as identified by a non-conformance, if applicable	B2.11.4.3
Investigation of occurrences	B2.12.5 Standards
Documentation of occurrences	B2.12.7 Standards
Validation of critical procedures	B2.14 Standards
Chain of custody, Chain of identity	B2.15 Standards
Oversight of visitors	B4.1.3
Safety related policies and procedures – edited to align with sections C and D	B4.2 Standards
Personal protective equipment requirements	B4.3
Labeling operations	B6.2 Standards
Use of critical equipment by trained personnel	B7.2.1
Temperature monitoring for transfer of inventory	B10.3.4
Critical electronic record systems, new requirement	B11.8.2
Interruption of operations	B12.1, B12.4 Standards, B12.5 Standards, B12.6 Standards

Changes by Section (continued)

PART C: COLLECTION STANDARDS	
Topic	**Related Standard(s)**
Safety related policies and procedures – aligned with B/D	C1.8 Standards
Additional policies and standard operating procedures requirements	C3.1.5, C3.1.15
Detailed requirements for SOPS	C3.2, C3.3 Standards
Informed consent	C4.5.12
Multiple gestation donor safety	C6.2.2
Shipping with continuous temperature monitoring	C7.5.3.1

PART D: PROCESSING STANDARDS	
Topic	**Related Standard(s)**
Safety related policies and procedures -edited to aligned with sections B and C	D1.7 Standards
Cord blood processing facility personnel requirements – new to Processing section to align with Part B	D.2 Standards
Additional policies and standard operating procedures requirements	D3.1.1, D3.1.4, D3.1.5, D3.1.7, D3.1.8, D3.1.9, D3.1.12
Controlled documents	D3.2
Procedures for qualified staff	D3.3 Standards
Processing per informed consent	D4.1.4 Standards
Storage and temperature monitoring for CB units not fully immersed in liquid nitrogen	D7.5.1.1
Alarm conditions	D8.4.4
Notification of personnel for alarms	D8.4.6.1
Disposition of units for commercial use	D9.1.6
Disposition of units without full consent	D9.4.2.3
Maternal donor consent	D9.4.3.3

Changes by Section (continued)

PART E: CORD BLOOD LISTING, SEARCH, SELECTION, RESERVATION, RELEASE, AND DISTRIBUTION STANDARDS	
Topic	**Related Standard(s)**
Verification of HLA typing	E1.2.3.4
Potency testing	E3.3 Standards
Transportation and shipping of cord blood units	E5.1
Liquid nitrogen cooled dry shippers	E5.4.1, E5.4.2
Record the condition of the package upon receipt	E6.3.6.1
Transportation and shipping from third-party manufacturers	E6.4
Requesting information for further processing	E7.1.1
Ex vivo expansion prior to administration	E7.1.8.3
Analysis of aggregate data	E7.3

APPENDICES		
Number/Name	**Topic**	**Change**
Appendix I: Key Personnel Requirements	CBB Director education and job responsibilities	Post-baccalaureate degree and years of experience
	Quality Unit Manager	Ensure compliance with the QM plan
Appendix II: Cord Blood Unit Labeling	Conditions for exceptional release	AC
Appendix III: Accompanying Documents at Distribution	National and international regulations apply	Footnote 5
Appendix IV: Testing Requirements	HLA-C	For unrelated only
	~~Low Resolution HLA-C~~	Deleted
	Verification typing	Footnote 2 edited, Footnote 6 new