Summary of Changes

Eighth Edition NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration, Version 8.2

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, Version 8.2* with the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration,* Version 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 was added to permit flexibility in the delegation of specific activities. Note: a tenet is a basic principle that is true throughout the Standards.	A2.2 The phrase "or designee" was removed from individual Standards throughout.
Revised definition: *Cellular therapy product*	Edited 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

Major Changes (continued)

Topic	Explanation	Related Standard(s)
New definition: *Exceptional release*	New term included to define a product that fails to meet specified criteria for distribution. This term is harmonized with the FACT-JACIE HCT Standards.	A4
New definition: *Eurocode*	New term included to specify those products with labels published by the Eurocode International Blood Labeling Systems. This term is harmonized with the FACT-JACIE HCT Standards.	A4
New definitions: *Good practices, GMP, GTP, and GxP*	Definitions added 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)**
Defined key personnel responsible for the aspects of Quality Management	B2.1.1, B2.2.1
Added GxP training requirements	B2.5.4.4
Change control — Additional requirement: Assessment of need to qualify equipment, supplies, or reagents	B2.6.5.1

Changes by Section (continued)

Topic	Related Standard(s)
Change control — Additional requirement: Change in practice shall not occur before a change control plan has been approved for implementation	B2.6.6.1
Additional requirement: Description of change when a document is amended	B2.7.4.1
Defined requirements for the review of controlled documents listed in B2.7.1 every two (2) years at a minimum	B2.7.7
Additional requirements for 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
New requirement for maintaining audit reports	B2.11.7
Expanded requirements for investigation of occurrences	B2.12.5 Standards
Expanded requirements for documentation of occurrences	B2.12.7 Standards
Expanded requirements for validation or verification of critical procedures	B2.14 Standards
Added Chain of custody and Chain of identity as part of CB linkage requirements	B2.15 Standards
New requirement for oversight of visitors	B4.1.3
Safety related policies and procedures edited to align with sections C and D	B4.2 Standards
Added personal protective equipment requirements	B4.3
New requirement for maintaining confidentiality of infant and maternal donor information	B5.7.2
Expanded requirements for labeling operations	B6.2 Standards
Added specific requirement on the use of critical equipment only by trained personnel	B7.2.1
New requirement for inventory records to include dates of storage and associated samples for the CB unit	B9.2.5
New requirement for temperature monitoring for transfer of inventory	B10.3.4
Expanded SOP requirements for critical electronic record systems	B11.8.2
Interruption of operations — reorganized and added specific detailed requirements	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 Parts 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 — additional requirement if the CB unit is potentially used for reasons other than transplantation	C4.5.12
Added requirement to perform an evaluation in the case of a multiple gestation pregnancy for in utero collections	C6.2.2
New requirement for shipping without 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
New requirement for list of controlled documents	D3.2
SOP requirements aligned with Parts B and C	D3.3 Standards
New requirement for processing per informed consent	D4.1.4 Standards
Revised requirements for storage and temperature monitoring for CB units not fully immersed in liquid nitrogen	D7.5.1.1
Revised requirement for alarm in case personnel is not always present	D8.4.4
Additional instructions for notification of personnel for alarms	D8.4.6.1
Additional disposition criteria — units for commercial use	D9.1.6
Additional disposition requirement — units without full consent	D9.4.2.3
Additional requirement for disposal of related CB	D9.4.3.3

Changes by Section (continued)

PART E: CORD BLOOD LISTING, SEARCH, SELECTION, RESERVATION, RELEASE, AND DISTRIBUTION STANDARDS	
Topic	**Related Standard(s)**
New requirement for verification of HLA typing of CB units for related use	E1.2.3.4
New Standard addressing potency testing	E3.3 Standards
New requirement for transportation and shipping of cord blood units as per Applicable Law	E5.1
Additional requirements for liquid nitrogen cooled dry shippers	E5.4.1, E5.4.2
Additional requirements to record the condition of the package upon receipt	E6.3.7
New requirement — Transportation and shipping from third-party manufacturers	E6.4
Revised requirement — Request for information related to processing or manipulation of the for CB unit	E7.1.1
Recommendation to collect information if ex vivo expansion occurs prior to administration	E7.1.8.3
New requirement for SOP for 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	Other national and international regulations may 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