

## CHANGES TO THIRD EDITION

The table below outlines the changes made to the *NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release* with each version of the third edition of these Standards.<sup>1</sup> This table can also be found as Appendix III in the Standards and Accreditation Manual.

Version Number <sup>2</sup>	Standard	Change
3.1	Definition of Fixed Collection Site	A collection site where there is a written agreement between the facility and the Cord Blood Bank Processing Facility for the collection of cord blood units. The agreement shall describe the interaction between the Collection Facility and the Cord Blood Bank for all aspects of the collection process including, at a minimum, personnel training, record keeping, collection, storage, and transportation of a cord blood unit.
3.1	Definition of Non-Fixed Collection Site	<del>Non-fixed Collection Site: A collection site without an ongoing, facility-based, documented agreement with a Cord Blood Bank where one or more cord blood units may be collected at the initiation of the donor's mother and/or family and with documentation that by a licensed medical professional who has agreed to perform the collection using materials provided by the Cord Blood Bank in a collection kit after completion and documentation of and training that covers each aspect of the collection process.</del>
3.1	A3.2.1.3	CBB Collection Facility Medical Director(s) and/or the designated individual at each <u>fixed collection site</u> Collection Facility not staffed by the CBB personnel, <u>or the collecting health care professional at the non-fixed site</u> , who is responsible for the daily operation of the Collection Facility and communication with the CBB Medical Director.
3.1	B3.2	The responsibilities of each Collection Facility, <u>collecting physician or midwife</u> , CBB Processing Facility, and Registry as they relate to the CBB shall be clearly defined and documented.
3.1	B3.3.1	For collection of <del>unrelated donor</del> CB units <u>at fixed collection sites</u> , there shall be an established relationship between the Collection Facility and the CBB such that the CBB ensures implementation of and compliance with its QM Program and Standard Operating Procedures for obtaining and documenting informed consent, maternal and infant donor screening and testing, completion of medical history, and the collection, labeling, and shipment of the CB unit and maternal samples.
3.1	B3.3.2	For collection of <del>directed allogeneic or autologous</del> CB units <u>at non-fixed collection sites</u> , the CBB shall have a written agreement with the infant donor family and shall have communicated with the collecting physician, midwife, or other healthcare professional. The CBB shall provide the appropriate policies, <del>and Standard Operating Procedures</del> , and materials for the collection, labeling, storage, packing, and shipment of the CB unit and maternal samples, and shall monitor the quality of the CB unit collections through its QM Program.
3.1	B7.2.3.1	A copy of mother's consent <u>or written agreement</u> for collection and, if available, a copy of the father's consent <u>or written agreement</u> for collection.
3.1	B7.2.3.2	A <del>contract</del> <u>written agreement</u> specifying duration of storage and possible uses of the CB unit and reference samples.
3.1	B7.2.3.3	Documentation of the agreement for disposition at the end of the <del>contract</del> <u>storage period</u> and the final disposition of the CB unit.
3.1	B7.2.4	<del>Directed allogeneic and autologous</del> Recipient and parental records for CB units collected in non-fixed Collection Sites.
3.1	C2.2 (new)	<u>A CBB may interact with fixed and/or non-fixed collection sites.</u>
3.1	C2.3 (new)	<u>CB units intended for unrelated allogeneic, directed allogeneic, or autologous use may be collected at either fixed or non-fixed collection sites.</u>
3.1	C2.4	<del>Unrelated allogeneic CB collections. Fixed Collection Site</del>
3.1	C2.4.1	There shall be documentation describing the agreement and interaction between the Fixed Collection Facility <del>Site</del> and the CBB.
3.1	C2.4.6	When collection activities at a Fixed Collection Facility <del>Site</del> are discontinued for period exceeding six months, Section B9 applies.
3.1	C2.5 (deleted)	<del>When directed allogeneic or autologous CB units are collected in a Fixed Collection Facility Site, Section C2.4 applies.</del>
3.1	C2.5	<del>When directed allogeneic or autologous CB units are collected in Non-Fixed Collection Facility Site.</del>
3.1	C2.5.1	<u>For autologous or directed donations</u> , there shall be a written agreement between the donor family and the CBB related to CB unit collection, transport, processing, testing, storage, and release.
3.1	C2.5.5 (new)	<u>When a collection kit is prepared and sent from the CBB, there shall be adequate instructions and materials provided to collect, store, pack, and ship the CB unit.</u>
3.1	C2.5.5.1 (new)	<u>The stability of temperature during shipment shall be validated or there shall be a mechanism to record the temperature of the kit from the time it leaves the CBB to the return of the kit to the CBB.</u>
3.1	C2.5.5.2 (new)	<u>Documentation of these parameters shall be provided to the bank and maintained in the CBU file.</u>
3.1	C3.1	The <del>CBB Fixed Collection Facility Site</del> shall have clearly written policies and procedures that are precise and unambiguous and that address all aspects of the collection operation, meet the requirements of these Standards, and are consistent with the Standard Operating Procedures of the CBB. Sections B2.1.1 and B2.2 also apply.
3.1	C3.2	All Collection Facility personnel shall follow the policies and Standard Operating Procedures established by the CBB.

<sup>1</sup>This appendix does not include minor numbering or reorganization changes that were a result of the substantive changes listed above.

<sup>2</sup>The effective date of version 3.1 is January 20, 2009.