FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

Request for Public Review and Comment
Draft Seventh Edition
NetCord-FACT International Standards for
Cord Blood Collection, Banking, and Release for Administration

The Foundation for the Accreditation of Cellular Therapy (FACT) published the draft Seventh Edition of the *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration* and accompanying Accreditation Manual for inspection and public comment for a 90-day period. Comments will be accepted from November 30, 2018 through March 1, 2019.

The Standards apply to all phases of cord blood collection, banking, and release for administration, including donor management, collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution to clinical programs. These Standards are comprehensive, and cover 1) collection of cord blood cells, regardless of the methodology or site of collection; 2) screening, testing, and eligibility determination of the maternal and infant donor according to Applicable Law; 3) all phases of processing, cryopreservation, and storage, 4) testing and characterization of the cord blood unit; 5) making the cord blood unit available for administration, either directly or through listing with a search registry; 6) the search process for selection of specific cord blood units; 7) reservation and release of cord blood units for clinical use; 8) transport or shipment of fresh or cryopreserved cord blood units, and 9) clinical follow up.

These Standards apply to the banking of placental and umbilical cord blood for clinical use in related or unrelated recipients, for research, or both. For cord tissue collection and storage, these Standards apply only to tissue samples retained for testing or research purposes. Collection and storage of cord tissue for therapeutic intent are processes within the scope of the *FACT Common Standards for Cellular Therapies*. Standards for the administration of allogeneic or autologous cord blood cells are included in the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*.

The final Standards will be published on October 15, 2019 and will become effective on January 15, 2020.

The draft is a redlined document intended to highlight the changes made to the Standards. Minor reorganization and clarifying changes are not tracked. Some changes are new standards; however, some are intended to clarify the intent rather than change the requirements. **This document is not an exhaustive list of changes made to the Standards. Refer to the draft Standards to review all changes**.

The Standards Committee invites comments and suggestions related to any standard, whether it is new, revised, or unchanged from the sixth edition. The following is a list of proposed changes for which the Standards Committee specifically requests comment.

1. The Sixth Edition NetCord-FACT Standards required that Cord Blood Banks (CBBs) be actively implementing ISBT 128. The seventh edition draft Standards requires that ISBT 128 or Eurocode be fully implemented. Appendix II, "Cord Blood Unit Labeling," has been updated to concisely convey requirements specific to both ISBT 128 and Eurocode. Do you have any comments regarding these requirements? (B6.1.2, Appendix II)

2. Use of supplies and reagents of the appropriate grade is currently required in the sixth edition Standards. The Accreditation Manual explains that if the appropriate grade of reagent is not used, lot-to-lot functional verification is required. The seventh edition draft Standards includes a proposed standard that requires lot-to-lot functional verification, including acceptance criteria to confirm new lots perform as expected compared to the previous lots. Informative guidance is based on review and comparison of labeling and accompanying documentation of various DMSO products in common use. Does this added information provide clarity? Do you have any other comments regarding this requirement? (B8.4.1)

3. The sixth edition requires measurement of viability of total nucleated cells or CD45 cells. In the seventh edition, CD45 cells must be measured and achieve ≥ 70% on fresh post-processing prior to cryopreservation samples. Do you have any comments on these edits? (Appendix IV, Appendix V)

Comments regarding the draft Seventh Edition NetCord-FACT Cord Blood Standards can be submitted by accessing the Comment Form. Comments will be accepted through March 1, 2019.