Request for Public Review and Comment
Draft Third Edition
FACT Common Standards for Cellular Therapies

The Foundation for the Accreditation of Cellular Therapy (FACT) published the draft third edition *FACT Common Standards for Cellular Therapies* at *http://www.factwebsite.org/publiccomments/* for public comment during a sixty-day period. Comments will be accepted through September 30, 2021.

These Standards represent the basic fundamentals of cellular therapy that can be applied to any cell source or therapeutic application and are intended to be used throughout cellular therapy product development and clinical trials.

The final Standards will be published in March 2022 and will become effective in June 2022.

The draft is a redline document intended to highlight the changes made to these 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. In addition, many changes were made to provide consistency among all sets of FACT Standards.

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 second edition. The following is a list of proposed changes for which the Standards Committee specifically requests comment:

1. The current second edition of the Common Standards requires that cellular therapy products be identified by ISBT 128 standard terminology. The proposed third edition also requires full implementation of ISBT 128 coding and labeling technology. (See draft Standards C7.1.2 and D7.1.2.) FACT supports the use of ISBT 128 to assign internationally unique identifiers for cellular therapy products, maintain chain of identity and chain of custody, and promote international exchange of information. More details about ISBT 128 can be found online at https://iccbba.org/. We request input on the relevance of this new requirement in the context of newer cellular therapies.

2. Many changes were made to the Quality Management sections in the draft third edition. (See Sections B4, C4, and D4.) Although most revisions do not change the intent of the requirements, some introduce new concepts such as annual GxP training. We request review of these sections and input on the appropriateness of the revisions.

3. A minimum number of collection procedures is proposed in the third edition. (See C1.5.) A minimum of five (5) cellular therapy products shall have been collected prior to initial accreditation, and a minimum average of five (5) cellular therapy products shall have

been collected per year within each accreditation cycle. Please comment on the feasibility of this requirement.

Instructions for Submitting Public Comments

To submit comments regarding the draft third edition FACT Common Standards at http://www.factwebsite.org/publiccomments/, follow the steps below. Comments will be accepted through September 30, 2021.

1. Access the Comment Form at https://redcap.nebraskamed.com/surveys/?s=4PRJMNAYCW

2. Enter your contact information and comments on the form. Fill in all fields to ensure the Standards Committee fully understands your position.

3. Submit the form when you are finished. Once the form has been submitted, it cannot be changed. However, additional comments may be submitted by completing the form again. There is no limit to the number of forms that can be submitted.