

Request for Public Review and Comment
Draft Sixth Edition
FACT-JACIE International Standards for
Cellular Therapy Product Collection, Processing, and Administration
for Hematopoietic Cellular Therapies

The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-EBMT (JACIE) have published the draft sixth edition of the [FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for Hematopoietic Cellular Therapies](#) for inspection and public comment for a 90-day period. Comments will be accepted from April 30, 2014 through July 24, 2014.

These Standards apply to all phases of collection, processing, storage, and administration of cellular therapy products (including hematopoietic progenitor cells and mononuclear cells) that have been derived from marrow, peripheral blood, umbilical cord blood, or placental blood for hematopoietic cellular therapies. These Standards do not apply to the collection, processing, or banking of umbilical cord or placental blood.

The draft is a redline document intended to highlight the changes made to the Standards. Minor reorganization and clarifying changes are not tracked. We caution reviewers that not all changes affect the intent of the requirements; rather, some changes are meant to improve the clarity or verbiage of a standard.

The final Standards will be published on March 1, 2015 and will become effective on May 30, 2015.

A description of the document and changes for which public comments are specifically requested are below. **This document is not an exhaustive list of changes made to the Standards. Refer to the draft Standards to review all changes.**

Global Changes to Standards

The following global changes were made to the documents:

1. The FACT-JACIE Standards include “Hematopoietic Cellular Therapies” in the title to define the scope of these requirements. Due to an increasing number of accredited facilities that support non-hematopoietic cellular therapies, and because of FACT’s separate regenerative medicine initiatives, this change is intended to clearly delineate what activities must comply with the Standards.
2. The Standards include a new format intended to visually group related standards and also modernize the text. Additionally, many standards that were used solely for organizational purposes but that did not have specific requirements were removed to make the document more brief. Header standards that facilitate comprehension remain.

3. Recommended practices that only result in a variance if not complied with are more prominent with “should” underlined.
4. The Processing Facility Standards were reorganized to separate the Process Controls section into more manageable sections of like requirements.

Specifically Requested Comments

The following is a list of significant changes to the Standards for which the Standards Committee specifically requests comments. This is not an exhaustive list of changes to the Standards, and reviewers are urged to consult the draft sixth edition *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration for Hematopoietic Cellular Therapies* for all the changes and comment as desired.

1. Minimum new patients for accreditation standards (Part B): The minimum numbers of new patients for Clinical Programs are now outlined in a table in Appendix I to concisely convey requirements. Public comments regarding the usefulness of this change and clarity of the table are requested.
2. ASHI, EFI, and other accrediting organizations (B2): The draft proposes a change from requiring the use of HLA typing laboratories accredited by ASHI, EFI, or other “equivalent” accrediting organizations to requiring the use of laboratories accredited by ASHI, EFI, or other organizations providing “appropriate” services related to the care of transplant patients. Public comments regarding the appropriateness of this change, and any supporting information, are requested.
3. Chimerism testing (B2): The draft Standards require that chimerism testing be performed in laboratories accredited for that service. Clinical decisions regarding the pace of withdrawal of post-transplant immunosuppression and/or subsequent administration of donor lymphocytes based on chimerism results may have potentially life-threatening consequences with respect to GVHD, relapse risk, or graft failure. Furthermore, chimerism testing may be performed with a variety of methods and interlaboratory variability may be significant. EFI and other organizations provide external laboratory accreditation and quality assurance in chimerism testing. Public comments regarding the feasibility of this requirement are requested.
4. Physicians-in-training (B3.4) and Pharmacists (B3.8): New sections were added to the Personnel section to include all key providers in a Clinical Program. Public comments regarding the addition of these requirements are requested.
5. Additional metrics for outcome analysis (B4.6.3): Clinical Programs are required to collect outcome data and analyze these data as part of the Quality Management Program. In addition to mortality, new metrics within 100 days after transplantation were added: acute Graft versus Host Disease (GVHD), assessed according to established

staging and grading systems, and central venous catheter infection. These requirements do not require benchmarking but an internal review of outcomes to identify potential opportunities for improvement. Both individual patient data and program aggregate data should be followed and evaluated. It is understood that measuring clinical outcomes is imprecise and few, if any, metrics adequately take into account the wide range of variables that programs may or may not be able to control. Public comments regarding the appropriateness of these, or other, metrics to facilitate quality improvement, and potential methods for tracking data are requested.

6. Pregnancy testing (B6.3, CM6.3, C6.3): Previous editions of standards required only a pregnancy assessment for female donors with childbearing potential, which was often misinterpreted. For clarification and to increase the safety of donors, the draft Standards propose requiring pregnancy testing. Public comments regarding the appropriateness of this requirement are requested.
7. Additional requirements for care of allogeneic recipients (B7.5): Standard of care has evolved in the assessment of allogeneic recipients for evidence of acute and chronic GVHD, vaccinations, post-transplant care, and post-transplant late effects. Public comments regarding the appropriateness of the additional requirements for allogeneic transplantation are requested.
8. Extracorporeal photochemotherapy (ECP) requirements (B7.7.2, C8.17): ECP requirements now include a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, organs involved, and proposed regimen. Public comments regarding whether these changes increase the clarity of the requirements are requested.
9. Continuing education (B3, CM3, C3, D3): Due to many questions regarding what constitutes "regular" participation in continuing education, the proposed Standards require a specified minimum number of continuing education hours for key personnel. These numbers are intended to relate solely to education on topics pertinent to the role personnel play in cellular therapy, and do not require formally recognized educational credits. Public comments regarding whether these prescribed numbers clarify the requirement and reduce ambiguities are requested.
10. Minimum number of marrow collection procedures (CM1.4): An increase in the minimum number of marrow collection procedures throughout the accreditation cycle from a minimum average of one to two marrow collection procedures per year is proposed. Public comments regarding the ability of organizations to meet this standard are requested.
11. ISBT 128 coding and labeling (CM7.1.2, C7.1.2, D7.1.2): The fifth edition required organizations to have a plan for ISBT 128 coding and labeling technology

implementation. The proposed sixth edition requires that organizations be actively implementing ISBT 128 coding and labeling technologies, demonstrated by:

- a. Registration with ICCBBA;
- b. Identification or creation of appropriate product codes;
- c. Label designs according to the requirements of ICCBBA for Cellular Therapy Products;
- d. Label validation;
- e. Use of scanned information at the time products are released from collection, received into the laboratory, and at distribution from the processing facility.

Public comments regarding the ability of organizations to comply with this standard are requested.

12. Central venous access (C8.10.1): The standard for verifying line placement has been interpreted to require imaging techniques. This has been reinforced by The American Society of Anesthesiologists Task Force on Central Venous Access and the S(P)EAR Alert regarding donor death due to a tension hemo/pneumothorax related to the insertion of a central venous catheter. Public comments regarding the appropriateness of this interpretation, and how different catheter sites may dictate necessary verification techniques, are requested.

13. Processing Facility requirements for emerging manufacturing (Part D): Several new standards in Part D address cellular therapy product processing in facilities with classified air (e.g., clean rooms), manipulation that may require compliance with U.S. 351 or EU ATMP regulations, or distribution to or receipt from third-party manufacturers. Public comments regarding the feasibility of these requirements are requested.

Instructions for Submitting Public Comments

To submit comments regarding the draft sixth edition FACT-JACIE Standards, follow the steps below. Comments will be accepted until July 24, 2014.

1. Access the Comment Form at <http://www.surveymonkey.com/s/HCTcomments>.
2. Type in your contact information and comments on the form. Fill in all fields so that the Standards Committee fully understands your position.
3. Submit the form when finished. Once the form is 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.