

## Changes to First Edition FACT Standards for Immune Effector Cells

The changes applied to the *FACT Standards for Immune Effector Cells*, Version 1.1 are outlined below. See Appendix IV in the *FACT Immune Effector Cells Accreditation Manual*, Version 1.1 for a summary of edits for the Accreditation Manual.<sup>1</sup>

### PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS

*Cytokine release syndrome*: A non-antigen-specific toxicity that occurs as a result of high-level immune activation. ~~For example, a reaction from the release of cytokines from cells targeted by an antibody or immune effector cells.~~

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### PART B: CLINICAL PROGRAM STANDARDS

B1.2 The Clinical Program shall use a cell collection process and processing facilities that meet FACT Standards with respect to their interactions with the Clinical Program.

B1.2.1 ~~If cellular therapy products are received directly by the Clinical Program or an intermediary facility receives cellular therapy products directly~~ from a third-party provider, the following responsibilities at a minimum shall be defined in a written agreement:

B1.2.1.1 Traceability and chain of custody of cellular therapy products.

B1.2.1.2 Cellular therapy product storage and distribution.

B1.2.1.3 Verification of cellular therapy product identity.

B1.2.1.4 Review and verification of product specifications provided by the manufacturer, if applicable.

B1.2.1.5 Readily available access to a summary of documents used to determine allogeneic donor eligibility.

B1.2.1.6 Documented evidence of donor eligibility screening and testing in accordance with applicable laws and regulations.

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B2.8 There shall be a pharmacy providing 24-hour availability of medications needed for the care of cellular therapy patients.

B2.8.1 Pharmacies shall have prompt access to medications adequate to treat expected complications of ~~immune effector cell administration~~ cellular therapy, including cytokine release syndrome.

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B3.8 PHARMACISTS

B3.8.1 Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.

B3.8.2 Training and knowledge shall include:

~~B3.8.2.1 An overview of Patient care, including~~ treatment for cytokine release syndrome and neurological toxicities.

~~B3.8.2.2 Adverse events, including but not limited to, cytokine release syndrome and neurological toxicities.~~

~~B3.8.2.3 Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive agents, anti-seizure medications, and anticoagulants.~~

~~B3.8.2.4 Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.~~

B3.8.2.5 Recognition of medications that require adjustment for organ dysfunction.

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B5.1 The Clinical Program shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these Standards and shall address at a minimum:

~~B5.1.8 Management of toxicities of immune effector cellular therapies, including~~ cytokine release syndrome and central nervous system ~~complications~~ toxicities.

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B7.6 There shall be policies and procedures addressing appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products, including, at a minimum, the management of the following elements:

~~B7.6.1 Management of nausea, vomiting, pain and other discomforts.~~

~~B7.6.2 Monitoring of blood counts and transfusion of blood products.~~

~~B7.6.3 Monitoring of infections and use of antimicrobials.~~

~~B7.6.4 Monitoring of organ dysfunction or failure and institution of treatment.~~

B7.6.5 ~~Allogeneic recipients should be assessed regularly~~ Regular assessment for evidence of acute GVHD using an established staging and grading system.

B7.6.6 ~~Allogeneic recipients should be assessed regularly~~ Regular assessment for evidence of chronic GVHD using an established staging and grading system.

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B7.8 There shall be an infrastructure and policies or Standard Operating Procedures in place for provision of appropriate long-term follow-up, treatment, and plans of care.

B7.8.1 There shall be policies or Standard Operating Procedures for monitoring by appropriate specialists of recipients for post-cellular therapy late effects.

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B9.2 The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.

B9.2.1 Defined data management staff should participate in continuing education annually.

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## **PART C: COLLECTION STANDARDS**

### **C3.2 QUALITY MANAGER**

C3.2.2 The Quality Manager of collection activities should have a reporting structure independent of cellular therapy product manufacturing.

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<sup>1</sup>The effective date of version 1.1 is May 30, 2018.