



News Release

Contact: Linda Miller
lmiller1@unmc.edu
402-559-1950

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FACT Publishes First Edition of Immune Effector Cell Standards

OMAHA, Neb. – The Foundation for the Accreditation of Cellular Therapy (FACT) is pleased to announce it has published standards for immune effector cells. The new requirements, included within interim standards for the sixth edition *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Collection, Processing, and Administration* and within the new, first edition *FACT Standards for Immune Effector Cells*, apply to cells used to modulate an immune response for therapeutic intent, such as dendritic cells, natural killer cells, T cells, and B cells. This includes chimeric antigen receptor T cells (CAR-T cells) and therapeutic vaccines.

The scope of the Standards includes donor selection and management, administration of cells, management of adverse events, and evaluation of clinical outcomes. The Standards require a quality management (QM) program that establishes, maintains, monitors, and implements improvements in the quality of facilities, processes, and performance.

These Standards were prepared with the understanding that some programs will be responsible for collection and processing of immune effector cells. Regardless of where the product comes from, the program must meet clearly defined responsibilities for chain of custody, storage, verification of product identity, and management of adverse events. To the extent that a program is responsible for collection of cells, manufacturing of the cellular therapy product, or preparing the product for administration, the collection and processing requirements in the FACT Immune Effector Cell Standards apply. The Standards are available electronically as a free download, or a printed copy can be purchased at www.factwebsite.org.

About FACT

Founded in 1996, FACT establishes standards for high quality patient care and laboratory practice in cellular therapies and regenerative medicine. FACT is a non-profit corporation co-founded by the International Society for Cellular Therapy (ISCT) and the American Society of Blood and Marrow Transplantation (ASBMT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy.

About FACT Accreditation

The accreditation process is designed to be supportive, consistent, and objective. FACT promotes improvement and progress by establishing minimum standards, providing education, and inspecting and accrediting programs worldwide. Expert inspectors and the comprehensive accreditation program verify programs provide high quality cellular products and help to achieve desirable outcomes for patients. For more information, visit www.factwebsite.org.

University of Nebraska Medical Center • 986065 Nebraska Medical Center • Omaha, Nebraska 68198-6065, USA
Tel: (402) 559-1950 • Fax: (402) 559-1951

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