

October 21, 2024

Craig Sauter, MD
 Program Director
 Cleveland Clinic Blood and Marrow Transplant Program
 9500 Euclid Avenue
 R-32
 Cleveland, OH 44195

Dear Dr. Sauter:

The Foundation for the Accreditation of Cellular Therapy (FACT) is pleased to award accreditation under the FACT-JACIE International Standards for Hematopoietic Cellular Therapy to Cleveland Clinic Blood and Marrow Transplant Program. The accreditation for your organization is effective for three years beginning October 21, 2024. This accreditation applies to all services and facilities that were inspected by FACT, specifically:

- Adult and pediatric allogeneic and autologous hematopoietic progenitor cellular therapy
- Immune effector cellular therapy
- Marrow cellular therapy product collection for administration
- Cellular therapy product collection by apheresis for administration and for further manufacturing
- Cellular therapy product processing with minimal manipulation

This letter and the corresponding Response Report are confidential. If you choose to share these documents with other parties (e.g., commercial companies manufacturing cellular therapy products), you should implement an agreement with the other party that specifies the intention of use and maintenance of confidentiality.

Please notify the FACT Accreditation Office if there are significant personnel, service, facility location, or contractual changes in your organization. Any new services provided by your organization within the accreditation cycle such as processing with more than minimal manipulation must be implemented in compliance with the FACT Standards and reported to FACT. If you use contracted services in your organization, you are responsible for monitoring the accreditation status of those contracted service providers and for notifying FACT of any change in providers.

FACT accredited organizations are required to complete an annual report one year after achieving accreditation. You will receive an annual report notification 30 days before the report is due. Your

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 Jacksonville, Florida

organization will be annually invoiced for FACT accreditation fees. Renewal accreditation is required every three years to maintain accredited status.

Accredited organizations are listed on the FACT website at <https://accredited.factglobal.org/>. FACT encourages your program to publicize its accreditation. A press kit is available to help communicate this accomplishment to patients, providers, insurance carriers, and other community stakeholders. The press kit includes a list of publicity strategies, a sample press release, and an electronic copy of the FACT Seal of Accreditation. If your organization would like to obtain the press kit materials, please complete the FACT Seal of Accreditation License Agreement. To complete the process and access the form, please contact FACT at 402-920-7001 or fact@factglobal.org. Note that if this accreditation is used in any advertising, you must specify the areas and services accredited as described above to accurately represent the activities accredited by FACT. We request that you refrain from linking this accreditation to unsubstantiated medical claims.

We encourage personnel at your organization to become FACT inspectors. Personnel who serve as FACT inspectors enjoy many benefits, including free access to FACT educational sessions, awareness of how other organizations comply with accreditation requirements, and increased exposure to the cellular therapy community. Organizations with inspectors have more impact on the development of standards and accreditation requirements. Information on how to apply to become a FACT inspector can be found at <https://www.factglobal.org/inspectors/>.

If you have not already, please provide us feedback regarding your FACT on-site inspection experience. This information is reviewed independently of accreditation decisions and helps us continuously improve. Feedback can be provided via the inspection evaluation available at <https://redcap.factglobal.org/surveys/?s=MN4TRYDFXKDHK43Y>.

Congratulations on achieving FACT accreditation and your continuing efforts to provide quality care and services. Please contact us at any time if there are questions, comments, or concerns. We will be happy to provide you with any additional information or assistance that you may need.

Sincerely,



Phyllis I. Warkentin, MD
Chief Medical Officer, FACT
Chair, FACT Accreditation Committee

Enclosure: FACT Accreditation Certificate

C: Swati Srivastava, MD
Ian Harrold, MD
William T. Tse, MD
Carolyn Mulroney, MD
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