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Accreditation Statistics

As of December 8, 2020

Cellular Therapy Entities

- Accredited: 240
- Applicants: 22

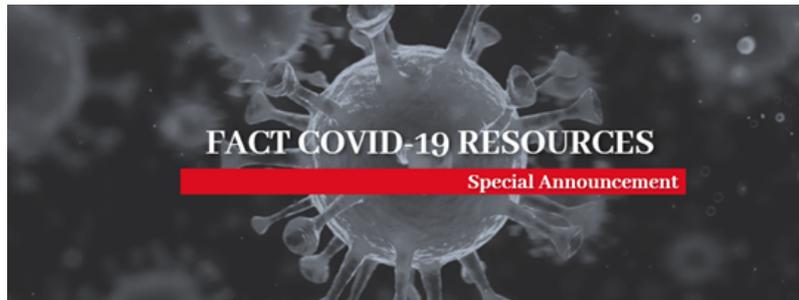
Cord Blood Banks

- Accredited: 57
- Applicants: 8

A complete list of accredited organizations can be found at www.factwebsite.org.

FACT Virtual Inspections in Response to COVID-19

Posted in :: 2020 Volume 8 :: Thursday, October 29th, 2020



FACT plans to begin virtual inspections this fall. There are many details to be finalized, however, the FACT Board of Directors has approved the plans outlined below. Thank you in advance for your flexibility and patience as we undertake this new process to protect the safety of our volunteer inspectors, personnel at accredited programs, and patients.

Eligibility for Virtual Inspections

Situations eligible for a virtual inspection include:

- Renewal accreditation inspections of clinical, apheresis, or cell processing programs applying independently or together as a hematopoietic cell transplantation program, including immune effector cells.
- Add-on service involving an existing accredited program (such as immune effector cells [IECs] or more than minimal manipulation processing).
- Reinspection of all or a portion of a program following Accreditation Committee review of an in-person inspection, provided at least one member of the original inspection team participates in the virtual inspection, and there were no citations related to the physical integrity of the location itself.

Situations not currently eligible for a virtual inspection, and for which an on-site inspection is required, include:

- Initial accreditation
- Addition of an entirely new service in a new space, such as a pediatric program at a Children's Hospital being added to an existing accredited adult program in another facility or a new current Good Manufacturing Practices (cGMP)-compliant processing facility added to an accredited transplant program.

In general, inspections will be either virtual or on-site, not a mixture. There may be exceptions. For example, an add-on to an existing program that is in the renewal process could have a virtual inspection for the renewal portion and an on-site visit of only the add-on portion (e.g., a cGMP facility for IECs added onto an accredited transplant program).

FACT is also working toward resuming some prioritized on-site inspections where these can be done in compliance with state, local, and CDC guidance and within facility and inspector restrictions. This applies primarily to new applicants.

Prioritization of Virtual Inspections

Priority for virtual inspections will be given to cellular therapy programs whose on-site inspections were canceled, then to those who were in the process of scheduling when the on-site inspections were suspended in March 2020. Cord Blood Banks will begin virtual inspections slightly later.

All programs have been given an additional 6-month extension of their accreditation expiration dates as we resume inspections in this new way. This represents a total of a one year extension to the accreditation expiration.

Preparing for Virtual Inspections

Programs will receive direct individual communications regarding additional documentation that will be required either as an extra annual report or additional pre-inspection updates, depending on where they are in the accreditation cycle.

Please watch for communication from your FACT Accreditation Coordinator. You may contact your FACT Accreditation Coordinator for additional information and share this information with other appropriate individuals in your program, including apheresis and cell processing services. Your Accreditation Coordinator's contact information can be found at http://www.factwebsite.org/About_FACT/FACT_Staff.aspx.

If you do not know who your coordinator is, contact Suzanne Birnley, Manager of Accreditation Services at suzanne.birnley@unmc.edu.

The Virtual Inspection Process

The platform for the interactive virtual inspections will be a FACT HIPAA-compliant ZOOM Healthcare account. There will be video tours expected, however, inspections will not be recorded. Video tours and additional documentation will be submitted through the FACT Accreditation Portal.

Cellular Therapy Program inspections will most likely occur over two days to allow both inspectors and program staff additional time to review and prepare additional documentation.

The Virtual Inspection Task Force is finalizing:

- The list of additional documents that will be submitted in advance.
- A list of documents that the program must be prepared to show to the inspector via ZOOM shared screen, which may include electronic documents such as SOPs, a portion of the EMR, or other scanned documents. Paper records may be shared via scanning or document or portable camera.
- A list of items that will be demonstrated via a video tour of each site.
- A proposed inspection agenda, including additional persons to be interviewed during the inspection, such as staff nurse, pharmacist, ICU / ER physician or staff.

Confidentiality of the Virtual Inspection

FACT has a Business Associate Agreement in place with each accredited and applicant program to cover confidentiality issues, including protected health information that may be viewed as part of the accreditation process, but is not recorded or retained by FACT or its volunteers. FACT's legal counsel has determined that the current Business Associate Agreement is sufficient to safeguard the virtual inspection process. FACT will work with any institution individually if there are concerns. All FACT staff and volunteers annually sign Confidentiality and Conflict of Interest Agreements.

In addition, the virtual inspection process will incorporate practices to enhance confidentiality, such as requirement for a private room for the inspector to conduct the inspection and lack of recording of the inspection.

Frequently Asked Questions

In addition to questions directly related to accreditation, FACT continues to receive questions related to patients, donors, and other COVID-19 related issues. A [Frequently Asked Questions](#) document is periodically updated and is available on the FACT website. Topics include:

- Rescheduled inspections
- Renewal process
- Allogeneic transplant numbers
- Relocating transplant patients
- Deviations
- Care adjustments related to COVID-19

If you have further questions or concerns, please contact [Dr. Phyllis Warkentin](#) [phyllis.warkentin@factglobal.org or 402-559-6781], the [FACT office](#) (402-559-1950), or your FACT Accreditation Coordinator.

Other Resources Available:

[ASTCT Resources](#)

[WMDA Resources](#)

[Centers for Disease Controls](#)

[World Health Organizations](#)

[NMDP/BeTheMatch](#)

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