FREQUENTLY ASKED QUESTIONS: FACT and COVID-19

1. Our on-site inspection was just postponed because of travel restrictions due to COVID 19. What happens if our accreditation expires?
No accreditation will lapse due to delays and postponements related to COVID-19. All currently accredited organizations will automatically receive a six-month extension of this accreditation cycle. This date will be further extended if circumstances require that action. New accreditation certificates will be provided.

The FACT website is the official source of the list of accredited organizations. Currently accredited organizations in the process of renewal or due for renewal will remain listed on the website during this period.

2. When will our inspection be rescheduled?
We will not be rescheduling on-site inspections until there is more information available about the timeline of this pandemic, when inspectors will be available and able to travel, and when sites will be ready to host visitors and an on-site inspection.

3. When our inspection is rescheduled, will we have the same inspection team?
FACT will make every effort to realign the same inspection team with the applicant program. This is especially important to inspectors who may have already been prepared for the inspection.

4. We are in the middle of the renewal process. What should we do?
To the extent possible, you should continue to submit documents and respond to Requests for Information (RFI) sent to you from your Accreditation Coordinator. FACT Accreditation Coordinators are available by phone or email to assist you. FACT understands that staff shortages and other demands during this COVID-19 pandemic may limit your ability to follow the usual timeline. Extensions of deadlines for response will be granted by your coordinator as needed on a case-by-case basis.

5. What will happen to our accreditation if our allogeneic transplant numbers fall below the minimum requirement in 2020 because our resources were stretched to accommodate COVID-19 issues?
Clinical treatment decisions, the availability of medications, donors, cellular therapy products, and clinical trials may each affect the number of stem cell transplant patients during the COVID-19 pandemic. FACT will make every effort to work with your program and make accreditation decisions on a case-by-case basis, in a reasoned and fair manner.

6. We may need to temporarily relocate our transplant patients due to COVID-19. What will FACT require us to submit related to relocation?
FACT is aware that health care facilities may face significant challenges in meeting the needs of all patients during this pandemic. Both inpatient and outpatient settings may be affected. Temporary relocations of cellular therapy patients based on institutional needs related to COVID-19 do not require immediate reporting to FACT. A description of the activities and the facilities utilized will be requested at the time of the Program’s Annual Report to FACT.
FACT expects that any temporary relocation of cellular therapy recipients or shifts in models of delivery of care should be undertaken to the extent possible using your Quality Plan and Clinical Standards as a guide. Considerations include a risk assessment of the alternate location, ensuring the facility is in an appropriate location with adequate space and protection from airborne microbial contamination, and that there is availability of appropriate medications, blood products, trained health care professionals, and additional care as required by these patients.

7. **What are the expectations of FACT related to deviations?**
   To the extent possible, management of deviations should follow usual quality management processes. Planned deviations from standard processes should be approved by the appropriate director or medical director, reviewed by the quality manager, and performed and documented in the usual manner. Unplanned deviations should be documented, investigated, reported, and a corrective action plan developed if appropriate, using the mechanisms described in your Quality Management Plan.

8. **How will FACT be treating care adjustments related to COVID-19?**
   Specific patient care recommendations are outside of the scope of FACT Standards. However, our parent society, the American Society for Transplantation and Cellular Therapy (ASTCT) and its Infectious Disease Special Interest Group have developed interim guidelines for COVID-19 management of HCT and cellular therapy patients. These will be updated as new information becomes available related to epidemiology, clinical outcomes, and efficacy of drug therapies: [https://www.astct.org/connect/astct-response-to-covid-19](https://www.astct.org/connect/astct-response-to-covid-19)

   EBMT has also published guidelines:

   The American Society of Clinical Oncology (ASCO) has also developed useful clinical guidelines related to caring for cancer patients in the context of the coronavirus pandemic: [https://www.asco.org/asco-coronavirus-information?cid=DM4750&bid=39975269](https://www.asco.org/asco-coronavirus-information?cid=DM4750&bid=39975269)

   In addition, FACT’s global partner The World Marrow Donor Association (WMDA) has provided blood and donor guidelines and resources for cord blood banking:
   - [Cord Blood Support Service](https://www.worldmarrow.org/cord-blood-support-service)
   - [Information specified per country (on restrictions on import/export)](https://www.worldmarrow.org/cord-blood-support-service)
   - [Donor suitability criteria](https://www.worldmarrow.org/cord-blood-support-service)
   - [European Centre for Disease Prevention and Control](https://www.ecdc.europa.eu/en/)

   Numerous other resources are available, including the [World Health Organization](https://www.who.int/) and the [Centers for Disease Control and Prevention](https://www.cdc.gov/).

9. **How should we screen donors for allogeneic transplant?**
   The potential risk of transmission of COVID-19 by blood or cellular therapy product infusion is unknown; however, respiratory viruses are not generally known to be transmitted by blood transfusion. Programs considering enhanced screening of potential donors should consult FDA guidance to provide donor education, encourage self-deferral as appropriate, and manage post-donation information about COVID-19. This includes considering deferral of donors who have
traveled to areas with COVID-19 outbreaks, lived with individuals diagnosed with COVID-19, or have themselves been diagnosed with or suspected of having COVID-19 infection. Based on limited information, deferral should last 28 days after resolution of symptoms or after return from an outbreak area. FDA will update these recommendations as more information becomes available.


Due to the uncertainty of the situation and the potential for additional travel bans, NMDP/Be The Match strongly recommends cryopreservation of adult donor products to allow for delivery of the product to the transplant facility prior to starting a recipient’s preparative regimen. Neither testing of donor products nor quarantine is currently recommended by NMDP or FDA. [https://network.bethematchclinical.org/news/nmdp/be-the-match-response-to-covid-19/](https://network.bethematchclinical.org/news/nmdp/be-the-match-response-to-covid-19/)

**FREQUENTLY ASKED QUESTIONS: Updated April 8, 2020**

10. Is the extension of our accreditation expiration date a permanent change or will our next accreditation cycle be shortened?

   The six-month extension in expiration date represents a permanent change to your program’s accreditation date and will be added to your current accreditation cycle. Your next accreditation cycle will be a full three years.

11. When will we get an updated Accreditation Certificate listing the new expiration date?

   FACT will send new Accreditation Certificates to all accredited organizations after scheduling of on-site inspections has resumed and extended timelines have been confirmed. If circumstances necessitate further delays, adjustments will be made to timelines. If a certificate is needed sooner, the Program Director should contact the FACT Accreditation Coordinator.

   The official list of FACT-accredited organizations and the services for which each is accredited is available at [www.factwebsite.org](http://www.factwebsite.org).

12. Is there an update to allogeneic donor screening and testing requirements for HCT/Ps? Should these donors be routinely tested for COVID-19?

   FDA continues to work with CDC and other federal and international agencies to monitor the evolving coronavirus pandemic. In Guidance issued April 1, 2020, FDA continues to recommend the routine screening measures already in place for evaluating potential HCT/P donors for clinical evidence of infection and to consider additional information related to COVID-19. This would include whether the potential donor had, in the previous 28 days, been diagnosed with or suspected of having COVID-19 infection or had had close contact with individuals diagnosed with or suspected of having COVID-19 infection.

   At this time, FDA does not recommend laboratory testing of asymptomatic HCT/P donors for COVID-19.
13. Our BMT Program is accredited for Immune Effector Cells. An Infectious Disease physician in our institution is considering opening a trial to treat patients with COVID-19 using an investigational cellular therapy product. The product is manufactured as an “off the shelf” product by a third-party manufacturer. The patients will not be transplant patients and will not be treated on the transplant unit. Does this trial fall under our HCT accreditation? 

In this scenario, the accredited program has no responsibility for procurement of the starting material or for manufacturing or administering the product. Among the many models of immune effector cell program structure, this would be considered to be a cellular therapy trial within the same institution, but not a part of the accredited program. The trial does not affect the BMT Program accreditation, even though the program is accredited for immune effector cells.

However, the FACT Standards for Immune Effector Cells are relevant to this sort of clinical trial. FACT recommends that physicians utilizing cellular therapies outside of the BMT unit consult and follow these Standards to the extent possible. In particular, aspects of quality management such as SOPs, training, appropriate facilities for the population being treated, good documentation practices, management of occurrences and adverse events, data management, and follow-up of clinical outcomes could contribute to the safe administration of these products. Transplant physicians with expertise in immune effector cells and their toxicities could offer valuable consultation. 

- Data management: CIBMTR through its Cellular Immunotherapy Data Resource may be interested in capturing these cellular therapy product infusions.
- Some patients with severe COVID-19 have been reported to have a cytokine release syndrome, a disorder with which physicians utilizing immune effector cells have familiarity.

14. What can we do if an allogeneic donor is suddenly unavailable for an urgent transplant?

The National Marrow Donor Program/BeTheMatch is currently requiring that all unrelated donor products be cryopreserved and shipped to the Transplant Center prior to initiating the recipient’s preparative regimen. Many transplant centers have begun this practice for related donors also. CIBMTR is currently analyzing data on the relative efficacy of fresh and cryopreserved grafts, with results expected soon. At least two experts have volunteered to assist if a facility is unfamiliar with cryopreservation of allogeneic marrow products. Their contact information is available at [http://www.aabb.org/advocacy/regulatorygovernment/Documents/Cryopreservation-of-Allogeneic-HPC-Marrow-Products.pdf](http://www.aabb.org/advocacy/regulatorygovernment/Documents/Cryopreservation-of-Allogeneic-HPC-Marrow-Products.pdf). Additionally, FACT Consulting is available. FACT-accredited facilities must follow all relevant standards related to change control for a new procedure, process validation, and personnel training.

If an alternative donor is not readily available, some programs are considering the use of cord blood grafts. Cord blood units are readily available for use, do not raise infectious disease questions related to coronavirus, and can be shipped without travel restrictions. NMDP/BeTheMatch has a Cord Blood Consultative Service for CB unit selection and is offering cord blood units from network banks for practice to programs unfamiliar with thawing and washing procedures. In addition, a presentation on thawing practices is available from NMDP/BeTheMatch: [Cord Blood Thawing Methods](http://www.aabb.org/advocacy/regulatorygovernment/Documents/Cryopreservation-of-Allogeneic-HPC-Marrow-Products.pdf).
15. Our Apheresis Department is developing workflows and protocols to facilitate virtual visits. Does FACT have any position on telemedicine in Apheresis?

Telemedicine is being implemented in many areas of medicine. Due to the COVID-19 pandemic, interest has grown rapidly to minimize the risk of transmission of infectious diseases between patients and medical staff, to reduce the need to travel for care, to preserve supplies of personal protective equipment, and to increase flexibility of the workforce. Telemedicine could also facilitate specialty care to patients who otherwise lack access due to geographic isolation or limited mobility. There are many HIPAA-compliant and suitable platforms and formats available to facilitate these visits. Many institutions have secure platforms for telemedicine embedded into the EMR. Laws, regulations, and institutional policies are variable across state and national boundaries. Although concerns related to reimbursement have been limiting, the Centers for Medicare & Medicaid Services (CMS) has recently expanded telehealth coverage and access by waiving certain requirements during this public health emergency.

While FACT has no standard that explicitly cites telemedicine, many Standards would apply to the application of these technologies in an accredited apheresis facility. These would include, but not be limited to, the responsibility to abide by applicable laws and regulations (C1.3), maintenance of a comprehensive system of document control (C4.5), policies and standard operating procedures to manage occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints) (C4.10), qualification of critical vendors and equipment (C4.13), electronic records (C11.7), policies and standard operating procedures addressing critical aspects of operations and management (C5.1), and staff training (C5.5). Standards related to donor and recipient confidentiality and issues of consent require particular attention when these actions occur in the telemedicine environment.