FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

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

EBMT has also published guidelines:
https://www.ebmt.org/ebmt/news/coronavirus-disease-covid-19-updated-ebmt-recommendations-8th-march-2020

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

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
- Information specified per country (on restrictions on import/export)
- Donor suitability criteria
- European Centre for Disease Prevention and Control

Numerous other resources are available, including the World Health Organization and the Centers for Disease Control and Prevention.

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.

- https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-blood-establishments-regarding-novel-coronavirus-outbreak
- https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments

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/