

FACT Report

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COVID-19 Update: FACT Accreditation

The health and safety of our cellular therapy community continues to be our utmost concern as we all work to mitigate the effect of the COVID-19 pandemic. Due to travel restrictions and CDC recommendations for social distancing, FACT has postponed all scheduled on-site inspections through June 30, 2020. Rescheduling of these and additional inspections will resume when an appropriate timeline can be determined. We will continue to follow recommendations from the CDC, health officials, and governmental agencies.

There have been many questions related to delays and postponements of on-site inspections due to travel restrictions and recommendations for social distancing.

Effective immediately, the accreditation expiration date for all FACT-accredited organizations will be extended by six months. This includes all clinical hematopoietic cell transplant programs, immune effector cell programs, apheresis centers, laboratory facilities, and cord blood banks, regardless of the current expiration date. This is our current best estimate of an appropriate timeline; however, if circumstances warrant, additional extensions will be implemented. New accreditation certificates will be prepared and distributed to eliminate confusion. The official list of accredited organizations is available at factwebsite.org.

To the extent possible, programs should continue to submit documents and complete Compliance Applications during this period when on-site inspections are not being scheduled. FACT staff are available by phone or email to receive and review this information and to provide other assistance as needed.

FACT also continues to receive questions related to patients, donors, and other COVID-19 related issues. A [Frequently Asked Questions](#) document is available at factwebsite.org.

For further questions or concerns, please contact Dr. Phyllis Warkentin, FACT Chief Medical Officer, at pwarkent@unmc.edu.

Canceled: FACT Cord Blood Inspection and Accreditation Workshop at ISCT Annual Meeting

The International Society of Gene and Cell Therapy (ISCT) has decided not to proceed with the ISCT 2020 **In-Person** Annual Meeting, originally scheduled May 27 – 30, 2020, in Paris, France, due to the coronavirus (COVID-19) outbreak. The ISCT 2020 Annual Meeting is rescheduled to take place virtually on May 28 and 29, 2020. The virtual meeting will be accessible remotely and on-demand, including live and recorded sessions that are certified for CME and CMLE accreditation in addition to networking events, poster halls, and 1-on-1 partnering opportunities. The highly curated ISCT 2020 virtual meeting program will leverage state-of-the-art virtual meeting technology to provide the full ISCT Annual Meeting experience that you expect from ISCT. For more details visit: <http://www.isct2020.com/>.

Because there will not be an in-person ISCT meeting, the associated FACT Cord Blood Inspection and Accreditation Workshop scheduled for May 26, and the ISCT-FACT Quality Boot Camp scheduled for May 27, 2020, have been cancelled.

If the FACT workshop is not rescheduled as a virtual session, your payment can be applied to the FACT workshop at the 2021 ISCT Meeting. If you prefer to receive a refund, please contact the FACT Business Manager, Jay Ann Witt at jawitt@unmc.edu.



2020 FACT-ASTCT Quality Manager Engagement and Resiliency Survey

Resilience is the ability to recover from or adjust easily to change. Highly resilient individuals thrive in an environment of change. The Quality Manager's capacity to be resilient during change, a constant in their work life, is a critical skillset.

Since 2017, the FACT Quality Management Committee and the ASTCT Administrative Directors SIG Quality Working Group have collaborated to identify opportunities to increase the Quality Manager's resiliency. During that year, the quality groups developed an anonymous survey to collect data on Quality Manager personal resilience and their perceived benefits of improved resilience. The survey included a validated "Brief Resilience Scale"² (BRS) which quantitatively measures resilience (1 = low to 5 = high).

To assess possible work stressors, Quality Managers were queried about their responsibilities, program size/complexity, and the nature of interactions with others (e.g., direct supervisors). Respondents were also asked to rank selected resources for increasing resiliency.

Since that initial survey, results have been analyzed and presented as abstracts during TCT | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR. Additionally, survey findings have been used to identify resources to help build resilience through improved workplace communications,

workload management, and other means. This resources list was uploaded to the FACT website at: <http://www.factwebsite.org/WorkArea/DownloadAsset.aspx?id=1898>.

It's come time to reassess...Quality managers, we need you!

The committees are reaching out more broadly to cellular therapy program and cord blood bank Quality Managers around the world requesting that you complete a follow-up survey. This year's anonymous survey takes approximately 20 minutes to complete. The survey can be accessed at the web address or by scanning the QRS code included below.

<https://www.surveymonkey.com/r/FACT-ASTCT2020QMResiliency>



The FACT Quality Management Committee and the ASTCT Administrative Directors SIG Quality Working Group plan to analyze information provided by respondents later this year and publish early in 2021.

Labeling and Chain of Custody for IEC Products presented by Dr. Sarah Nikiforow

Wednesday, April 22, 2020

11:00 am ET, 15:00 GMT

Dr. Sarah Nikiforow from Dana-Farber Cancer Institute / Cell Manipulation Core Facility, will present *Labeling and Chain of Identity and Custody for IEC Products*. Dr. Nikiforow will review the IEC Standards related to labeling and chain of identity and custody. Also, she will discuss FACT expectations for clinical trial research product labeling and chain of custody from bench to bedside. Finally, she will describe how ISBT 128 coding and labeling can be used with commercial cellular therapy products.

[Register now](#)

Integration of Immune Effector Cellular Therapy into a FACT-Accredited Transplant Program presented by Dr. Carlos Bachier

June 17, 2020

11:00 am ET, 15:00 GMT

Dr. Carlos Bachier, Program Director and Processing Facility Director at Sarah Cannon Blood and Marrow Transplant Program in Nashville, will present *Integration of Immune Effector Cellular Therapy into a FACT-Accredited Transplant Program*. Dr. Bachier will discuss the FACT Standards required for transplantation and immune effector cellular therapy. He will highlight opportunities and challenges when incorporating immune effector cellular therapy into an existing Quality Management Plan and provide steps that can be taken to incorporate immune effector cellular therapy into a transplant program.

[Register now](#)

FACT Cord Blood Inspection and Accreditation Workshop at the 2020 Cord Blood Connect International Congress on Hold

Given the rapidly evolving COVID-19 pandemic, a temporary moratorium has been placed on pre-registrations for the Cord Blood Connect international congress, scheduled for Sept. 10-12 in Miami Beach. The acceptance of abstracts also has been suspended while CBA leaders continue to assess the viability of this year's congress.

For the same considerations, registrations for the FACT Cord Blood Inspection and Accreditation Workshop scheduled for September 9, 2020, are also on a temporary hold. Options being evaluated include re-scheduling as well as alternatives for the in-person conference. Updates will be provided by FACT as information is made available.