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International Society ISCT Cell & Gene Therapy

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MEMBER NEWSLETTER

FACT Report

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Joint Statement from ASTCT, CIBMTR, FACT, ISCT and EBMT

Racism has no place in our society and profession. The American Society for Transplantation and Cellular Therapy (ASTCT), the Center for International Blood and Marrow Transplant Research (CIBMTR), Foundation for the Accreditation of Cellular Therapy (FACT), the International Society for Cell & Gene Therapy (ISCT), and the European Society for Blood and Marrow Transplantation (EBMT) all find these acts of racism reprehensible and inexcusable. This cannot be ignored any longer by the global community and our respective organizations.

We stand for the advancement of innovative, life-saving medicine. We know the importance of moving the needle forward in order to enact positive, powerful change. When it comes to issues of racism and violence, we realize the need for change, too.

We recognize that racism is an institutional problem in health care, and we are committed to doing our part to bridge that gap. We stand behind those who promote equality, diversity and inclusion. As a health care community, we have to do better—for not only the patients we serve, but the communities they live in as well.

As we work toward improving diversity and denouncing racism in health care and cities around the world, we commit to having the important conversations and supporting critical initiatives within our community that move us toward equality both in the transplantation, cellular and gene therapy workforce and in access to lifesaving therapies.

Please use this resource from the National Museum of African American History & Culture to educate yourself on the importance of talking about race and to find tools on combating racism in your own communities. We ask that you stand with us in denouncing racism and violence.

FACT Announces New Quality Management Series, Module 10: Validations

The Quality Management Series Module 10 includes four sessions focused on Validation including:

1. **Validation Overview**
   Presented by Nicole Prokopishyn, PhD

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August 19, 2020, 11:00 am ET, 15:00 GMT

Dr. Prokopishyn will discuss the difference between Validation, Verification, and Qualification, including Process Validation of immune effector cells, cord blood banking, apheresis, clinical, and processing.

Register now

2. **Process Validation**
   Presented by Jacklyn Stentz MT (ASCP) and Deborah Griffin MS, ASQ CPGP
   October 14, 2020, 11:00 am ET, 15:00 GMT

   Presenters will discuss the following:

   - Range to validate (where to start and when to stop), variables and extreme scenarios
   - Process validations (to include Bone Marrow process)
   - Verification: when is it needed

   Register now

3. **Software Validation**
   Presented by Robyn Rodwell, PhD and Guy Klamer, PhD
   December 2, 2020, 4:00 pm ET, 21:00 GMT

   Dr. Rodwell and Dr. Klamer will discuss the use of software validation as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures. Other topics include:

   - Critical electronic systems under the control of the organization (facility)
   - Spreadsheets
   - Vendor and organization responsibilities

   Register now

4. **Program Perspective on Validation**
   TBA

Register for the entire module to receive a 15% discount! **QM Series Module 10: Validations**

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New Immune Effector Cellular Therapy Webinar: *Bringing a Stand-Alone Immune Effector Cell Therapy Program into FACT Compliance*

Register now:

Bringing a Stand-Alone Immune Effector Cell therapy Program into Compliance

FACT Cord Blood Inspection and Accreditation Workshop at the 2020 Cord Blood Connect International Congress Officially Cancelled

The CBA Board of Directors has announced that this year's Cord Blood Connect international congress will be a virtual event. The directors agreed that the risks to participant health and safety in the midst of a worldwide pandemic are just too great for the planned in-person gathering. The congress was scheduled for Sept. 10-12 in Miami Beach and will now be held virtually on two non-consecutive days, Sept. 10 and 17. For more information, please visit the Cord Blood Virtual Connect meeting website.

Because the Cord Blood Connect international congress will now be a virtual event, the in-person FACT Cord Blood Inspection and Accreditation Workshop scheduled for September 9, 2020, is cancelled.

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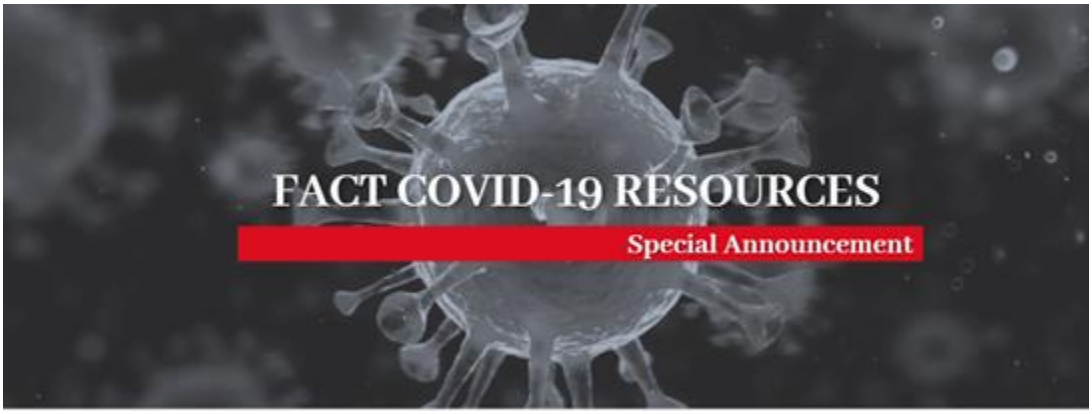

COVID-19 Update: FACT Accreditation

FACT continues to receive questions related to patients, donors, and other COVID-19 related issues; therefore, we will provide weekly updates to the Frequently Asked Questions document available on the FACT website.

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.

Guidance for Autologous Transplant Patients

Is there any specific guidance for autologous transplant patients, specifically about screening for COVID-19, documentation of screening, sedation, and other issues?

- For documentation of screening of autologous transplant patients prior to transplant, prior to collection of the hematopoietic cellular therapy product, or prior to a clinic or apheresis visit, FACT recommends this documentation follow routine medical record documentation practices.
- There may be specific institutional screening policies that should also be followed. Programs that want to implement enhanced screening for COVID-19 prior to collection of autologous HCT/Ps should follow FDA recommendation to include questions whether in the previous 28 days, the patient/donor has:
    - Cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or
    - Been diagnosed with or suspected of having COVID19 infection.

For specific guidance about sedation, medications, consideration for delay of transplant, or other clinical issues, refer to the recently updated ASTCT Interim Guidelines for COVID-19 Management in Hematopoietic Cell Transplant and Cellular Therapy Patients at: https://higherlogicdownload.s3.amazonaws.com/ASBMT/a1e2ac9a-36d2-4e23-945c-

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45118b667268/UploadedImages/COVID-19_Interim_Patient_Guidelines_4_20_20.pdf [higherlogicdownload.s3.amazonaws.com]

Written Agreements

- **HPC products destined for our clinical program are being cryopreserved at the collection center or occasionally by a third party facility due to COVID-19 travel restrictions and other concerns. Is our program expected to have written agreements in place to be in compliance with standards B4.6.1 and D12.1.1?**

  Presumably these products are unrelated donor products facilitated by a donor registry. Most likely, any single program will receive only one such product from a specific collection site or cryopreservation facility. This makes it impractical to have an individual written agreement in place with each collection or cryopreservation facility. FACT would consider these services of cryopreservation and shipment to be an extension of the program's written agreement with the Donor Registry.

  When our laboratory cryopreserves an unrelated donor product for another transplant center, what records should we include with the shipment?

  FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Seventh Edition, require [D13.5.2] the Processing Facility to provide "a copy of all records relating to the collection, processing, and storage procedures performed related to the safety, purity, or potency of the cellular therapy product". This would include at a minimum, the volume, total nucleated cell count, cell viability, CD34+ and CD3+ cell counts if performed, microbial culture results, testing, processing, and cryopreservation methods, identification and quantification of additives and cryoprotectants, and the freezing curve. The Processing Facility records should also identify any other facility participating in the collection or processing, and the extent of its responsibility [D13.5.3].

  In addition, the Donor Registry will provide registry-specific product analysis forms and potentially, additional data forms related to collection, processing, or storage that should be included with the product shipment. Data required will include identifiers for the donor and recipient, collection date, and product characteristics, including anticoagulants, additives, and the results of all testing performed.

  If the Collection Center or Laboratory providing products to an accredited Clinical Program is not FACT or JACIE accredited, the Clinical Program may have to specifically request processing information, including the data listed above.

  Laboratories undertaking cryopreservation for another transplant program should obtain recipient information necessary to perform the optimal pre-cryopreservation processing. Particularly in the case of bone marrow products, documentation of the donor and recipient ABO group is critical to ensure red cell reduction strategies are used prior to cryopreservation in the case of incompatibility.

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Frequently Asked Questions

Other topics addressed in the **FAQ document** include:

- Donor Screening for Allogeneic Transplants
- Written Agreements
- Unrelated Donor Products
- Annual Report
- Accreditation Extension
- Updated Accreditation Certificate
- Allogeneic Donor Screening and Testing Requirements
- COVID-19 Trials and HCT Accreditation

If you have further questions or concerns, please contact **Dr. Phyllis Warkentin** (402-559-6781), or the **FACT office** (402-559-1950).

Other Resources Available:

- **ASTCT Resources**
- **WMDA Resources**
- **Be the Match Resources**
- **Centers for Disease Control**
- **World Health Organization**

FACT Accreditation a Criterion for 2020-2021 Best Children's Hospitals List

U.S. News & World Report, published the 2020-2021 Best Children's Hospitals rankings and FACT accreditation was again used as a ranking criterion for the cancer specialty. For the Best Children's Hospitals list, one point was given for the Cancer specialty if a hospital is autologous only FACT-accredited and two points were given for allogeneic and autologous accreditation.

To accompany the rankings, U.S. News launched the U.S. News Hospital Heroes project, a series of profiles spotlighting the extraordinary efforts being mounted by health professionals in the trenches of fighting the historic coronavirus pandemic. U.S. News will share their experiences, hopes and fears from all corners of the hospital and broader public health landscape, as the country reopens and navigates the road ahead.

Heat-sealing label in cryopreservation bag pouch meets definition of "Affix"

The Accreditation Committees recently affirmed that inserting a label into a cryopreservation bag pouch and heat-sealing the pouch would categorize the contents (label) as affixed. When the definitions of

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"affix" and "attached" were written, the goal was to distinguish labels connected to the bag with a physical intermediary device (e.g., plastic, string, or metal linkage) from a label that was integral to the bag (e.g., direct bag to label contact). While glue is the most common method, we interpret that a sealed portion of the bag containing the label is equivalent to secure direct contact between bag and label.

Affix: To adhere in physical contact with the cellular therapy product container.
Attach: To fasten securely to the cellular therapy product container by means of a tie tag or comparable alternative. Any information required to be attached to a cellular therapy product container may alternatively be affixed.