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FACT Update, April 2021

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FACT PURSUES INDEPENDENT OPERATIONAL STATUS

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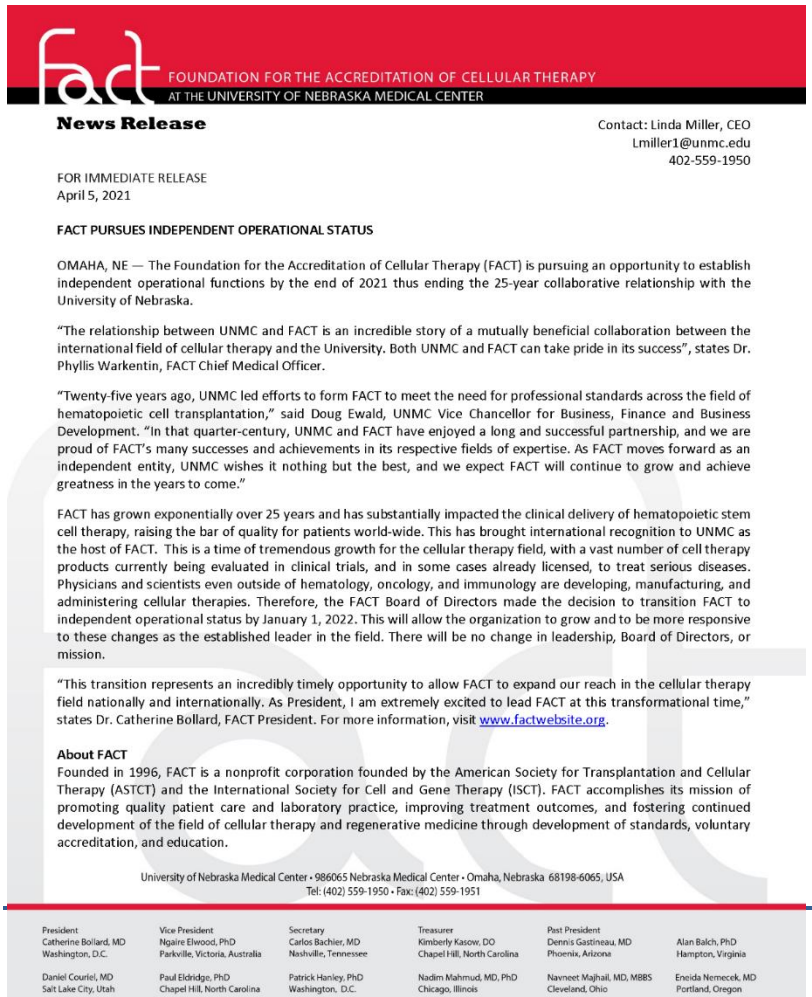

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

News Release

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FOR IMMEDIATE RELEASE
April 5, 2021

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"Twenty-five years ago, UNMC led efforts to form FACT to meet the need for professional standards across the field of hematopoietic cell transplantation," said Doug Ewald, UNMC Vice Chancellor for Business, Finance and Business Development. "In that quarter-century, UNMC and FACT have enjoyed a long and successful partnership, and we are proud of FACT's many successes and achievements in its respective fields of expertise. As FACT moves forward as an independent entity, UNMC wishes it nothing but the best, and we expect FACT will continue to grow and achieve greatness in the years to come."

FACT has grown exponentially over 25 years and has substantially impacted the clinical delivery of hematopoietic stem cell therapy, raising the bar of quality for patients world-wide. This has brought international recognition to UNMC as the host of FACT. This is a time of tremendous growth for the cellular therapy field, with a vast number of cell therapy products currently being evaluated in clinical trials, and in some cases already licensed, to treat serious diseases. Physicians and scientists even outside of hematology, oncology, and immunology are developing, manufacturing, and administering cellular therapies. Therefore, the FACT Board of Directors made the decision to transition FACT to independent operational status by January 1, 2022. This will allow the organization to grow and to be more responsive to these changes as the established leader in the field. There will be no change in leadership, Board of Directors, or mission.

"This transition represents an incredibly timely opportunity to allow FACT to expand our reach in the cellular therapy field nationally and internationally. As President, I am extremely excited to lead FACT at this transformational time," states Dr. Catherine Bollard, FACT President. For more information, visit www.factwebsite.org.

About FACT
Founded in 1996, FACT is a nonprofit corporation founded by the American Society for Transplantation and Cellular Therapy (ASTCT) and the International Society for Cell and Gene Therapy (ISCT). FACT accomplishes its mission of promoting quality patient care and laboratory practice, improving treatment outcomes, and fostering continued development of the field of cellular therapy and regenerative medicine through development of standards, voluntary accreditation, and education.

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Happy 25th Anniversary to the FACT Community!

Join FACT in celebrating 25 years of working together to improve the fields of cellular therapy, cord blood banking, and regenerative medicine. Congratulations to all FACT's volunteer inspectors, committee members, leadership, accredited organizations, staff, and supporters for making this milestone possible.

We invite readers to sign our 25th Anniversary Guest Book and leave a greeting, photo, or video. Additional celebratory events and activities will take place throughout the year.

Register *Now* for the FACT Inspection & Accreditation Workshop and Quality Boot Camp in Partnership with ASFA and ISCT!

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FACT Virtual Register for Workshop date Register for Boot Camp

Virtual inspections are currently being scheduled for those programs whose renewal accreditation process was interrupted in March 2020 due to pandemic-related issues. FACT Accreditation Coordinators have communicated information about the process to the Program Directors, Quality Managers, and the primary contact persons at those Cellular Therapy Programs whose inspections were canceled and those that were being scheduled. The FACT Business Manager Is currently contacting these Programs for potential inspection dates with the goal of completing the renewal process prior to the expiration date of the current accreditation for each Program.

FACT has created a Virtual Inspection Resource page on the FACT website at: http://www.factwebsite.org/virtualinspections/. Numerous documents have been updated and are available there, including guidelines for applicants and inspectors, technology guides, and examples of timelines and agendas. By popular request, a new OneNote template to organize compliance documentation has been developed for the 7th Edition FACT-JACIE Hematopoietic Standards for Cellular Therapy. Additional resources will be added to this page as they become available.

Following two successful pilot virtual inspections, participating program personnel, volunteer inspectors, and FACT staff identified several best practices for a virtual inspection and issues for process improvement. Several topics were identified as key to the success of the virtual inspection process. Best practices include:

Organization is key. Using OneNote to organize documents was an extremely helpful tool for both program personnel and inspectors. In OneNote, SOPs, policies, and other supporting documents and examples are linked directly to the specific FACT Standard and checklist question, making demonstration of compliance efficient and clear. FACT has created a OneNote template containing the 7th Edition FACT-JACIE Hematopoietic Cellular Therapy Standards that is now available on the Virtual Inspection Resources page.

The pilot inspection teams identified several additional documents that would have been very helpful to review in advance of the inspection. While FACT had not planned to require additional submitted documents, this recommendation is an important process improvement to be implemented immediately. Additional documents should be submitted in the FACT Portal via the Virtual Inspection Documents tab of the Document Library, identified by the relevant Standard number at the beginning of the document title. New documents include:

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Any policy or SOP specifically referenced in the Quality Management Plan.

The most recent Annual Report on the Effectiveness of the Quality Management Program. A list of documents has been added to the Applicant Guidelines in the Virtual Inspection Resource Center.

Be prepared to demonstrate tracking and tracing of products and processes from donor identification through product collection, processing, storage, and administration.

It is recommended that each person participate in the inspection at a separate computer to facilitate efficient responses. Having the applicant team together in one conference room is suitable if all attendees are able to see and hear sufficiently; however, it is easiest if participants are in separate rooms or adequately socially distanced to avoid the need for masks that tend to inhibit communication.

If more than one area (for example, both the adult and pediatric clinical programs, or clinical, apheresis, cell processing) uses the same Quality Management Plan, the applicant program should consider jointly reviewing the Quality Management section with all relevant inspectors. This should be included in the agenda when it is created and shared with the inspection team prior to the inspection.

FACT is pleased that the pilot virtual inspections were successful, and the lessons learned can be applied to ongoing renewal inspections. For initial applicants, or programs with a new service or space being added, an on-site inspection will be required. FACT continues to monitor inspector availability for travel and will schedule in-person inspections when applicants are prepared, and inspectors are available. Virtual inspections for cord blood banks will begin later this spring

Learning from Each Other: Accredited Organizations' Advice for Preparing for FACT Inspections

By Stacy Freeburg, FACT Accreditation Coordinator

FACT accreditation is the threshold for excellence in cellular therapy, including blood and marrow transplantation, immune effector cellular therapy, and cord blood banking. FACT-accredited organizations voluntarily seek and maintain FACT accreditation via a rigorous process, demonstrating their commitment to quality and their belief that patient needs are paramount. Obtaining and maintaining FACT Accreditation is a major undertaking.

Recognizing that we are a peer-driven organization and beginning to resume inspections, we invited a few organizations who are currently FACT accredited to share their suggestions for obtaining and maintaining FACT accreditation. In this article, we focus on improvements programs made to their accreditation preparation based on their experience.

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What changes did you make after accreditation was awarded to make the next cycle a bit easier?

Richard Makin, Immune Effector Cell Quality Manager, The Children's Hospital at Westmead Blood and Marrow Transplant Service

– A big one is START EARLY. When completing the Compliance Application, we try to get our documents as up to date as possible in the months beforehand so we do not make any changes when submitting documents. It is too hard to do in parallel and too time consuming. It is not really meeting the expectation of compliance either: documents and procedures need to be in active use when the inspectors come to assess.

– Conduct regular FACT meetings. We have monthly FACT meetings throughout the accreditation cycle on top of the quarterly large meeting where we summarize the majority of the quality system elements.

– We have found reviewing Immune Effector Cell data every 2nd Quarterly Quality Meeting useful. This has enabled us to get enough data on efficacy and outcome. It also gives us more time to drill down to the significance of results.

– The pediatric ANZCHOG (now TACTIC) annual meeting (Australia + New Zealand) has been a key meeting for reviewing patient outcomes. This is really well supported by our registry (Australasian Bone Marrow Transplant Recipient Registry), who provides sites specific reports. Each center provides an overview of all their patients and treatments used. The meeting has expanded to include nurses, quality managers, data managers, pharmacists, and scientists in addition to the treating physicians. This is excellent for real-world data analysis, collaboration, and continuing education.

– The annual report of quality activities has been a very useful tool for quality improvement and has grown to many pages. Again, we need to start early as it takes a long time to compile.

– Our registry has been very helpful in working with us on benchmarking outcomes. When this became a requirement a few years back, we sat down and came up with a plan. Now they have standard database report with indications, transplant numbers, engraftment, GVHD, and survival graphs comparing other sites in Australia and New Zealand. This has helped a lot rather than analyzing ourselves.

Elisha Nixon, Quality Program Manager, Walter Reed National Military Medical Center, Murtha Cancer Center Research Program, Uniformed Services University of the Health Sciences, The Henry M. Jackson Foundation

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After our program identified significant deficiencies during our FACT inspection in October 2016, a new Quality Manager was brought on board to revamp the entire program. Processes within the administrative, clinical, and laboratory processes were all modified to a significant extent. Following re-inspection, our program was granted re-accreditation in March 2018. Failure was not an option, and a change in mindset helped staff recognize that every Request for Information (RFI) was an opportunity to improve to guide us towards success.

Three years later, we have successfully maintained a program following best practices within the organization. We strive for continuous survey readiness because we learned a very hard lesson. While falling hard is rough on everyone, learning from those mistakes and implementing solid processes helped our program become even better than we could have imagined.

Melissa Henson BS, RN, OCN, Manager, Cellular Therapy and Leukemia Program, The Blood and Marrow Transplant/Leukemia Program, Northside Hospital Cancer Institute and

Ashlee Holbein, RN, FACT/QI Coordinator, The Blood and Marrow Transplant Program at Northside Hospital

To demonstrate standard compliance for the inspector, each department maintains a shadow notebook to allow for an efficient and smooth review of evidence. The shadow notebook is comprised of tabbed sections of each standard applicable for a department, including a title page and any supporting documents behind the corresponding tab. During our past two accreditation cycles, our program found the shadow notebooks immensely diminished time spent paging through documents. The shadow notebooks eliminate the need to visit multiple sources, specifically in situations when a standard impacts more than one area of the program. A key factor for the development and organization of the shadow notebooks is consistent mock FACT inspections with physician leadership and individual department quality designees.

FACT mock inspections are scheduled with all program departments to provide a format to meet collectively to review all FACT standards. The collective review of the FACT standards allows time for brainstorming and discussion of standard implications across various areas of the program.

Do you have any example approaches for maintaining compliance with the various standards?

Melissa Henson BS, RN, OCN, Manager, Cellular Therapy and Leukemia Program, The Blood and Marrow Transplant/Leukemia Program, Northside Hospital Cancer Institute and

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Ashlee Holbein, RN, FACT/QI Coordinator, The Blood and Marrow Transplant Program at Northside Hospital.

FACT standards are at the forefront of any discussion regarding updating a process or procedure. The first question is always, "What does the FACT standard say?" Daily, weekly, monthly, quarterly, and annual audits are used to ensure compliance throughout the accreditation cycle. Certain key standards are incorporated into quarterly programmatic quality improvement meetings to provide an overview of compliance to the program.

Richard Makin, Immune Effector Cell Quality Manager, The Children's Hospital at Westmead Blood and Marrow Transplant Service

Our routine audit cycle focuses on standard FACT topics and is expanded to assess the implementation of new requirements. When new standards are published, we do a gap analysis against our current SOPs and processes. We do this informally when FACT circulates the drafts and formalize when active.

In summary:

Continuous readiness is the goal of all organizations, which means that 1) actual practice matches what is in the approved policies and procedures and 2) there is a mechanism, such as an audit, to verify implementation. It is critical that programs build systems that assure that compliance can be maintained with accreditation standards on an ongoing basis. A common theme from the suggestions is including the FACT Standards as part of discussions on a quarterly, monthly, and daily basis. Regularly looking at the FACT Standards while discussing new processes and procedures allows an organization to address issues and act on them in a timely manner.

Tools available on FACT's web page:

When a new edition of the Standards is implemented, the FACT web page at http://www.factwebsite.org/standards/ is updated to include a summary of the changes from the previous edition. Also posted on this site are updated documents such as document submission requirements and other self-assessment tools.

In the webinar, Using an Electronic Platform for Accreditation Preparation and Continuous Readiness, presenters provided step-by-step instructions on how to build a OneNote FACT e-binder and organize evidence to be used for continuous readiness or as a platform to deliver evidence to the FACT inspection team. The webinar is available at http://www.factweb.org/forms/store/ProductFormPublic/using-an-electronic-platform-for-accreditation-preparation-and-continuous-readiness-webinar.