

Draft 5th Edition Cellular Therapy Standards Available for Public Comment

The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-EBMT (JACIE) have published the [draft 5th Edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration](#) and its accompanying [Accreditation Manual](#) for inspection and public comment for a 90-day period. Comments will be accepted through July 14, 2011.

Please review the [Request for Public Review and Comment](#) for a description of the documents available for review and a discussion of changes made to the Standards. To submit comments:

1. Download the [Comment Form](#).
2. Type in your contact information and comments on the form.
3. Save the Comment Form to your computer.
4. Email the comment form to fact@unmc.edu (Attention: Kara Wacker).

The final Standards will be published on March 1, 2012 and will become effective on May 30, 2012.

Letter from the President

This newsletter includes an article announcing the recognition by the American Society of Association Executives of FACT's process for implementing its strategic plans. As outlined by Alan Leahigh, FACT has enjoyed success with its strategic planning process for two reasons. The first reason is the attention we give to our strategic plan so that it is a living document integrated into all we do. Perhaps the culture of continuous improvement that drives our organization impacts this behavior in that once we reach a particular goal we are in search of new directions. The second, and more important, reason is you. Volunteers in the FACT community devote their time and expertise on committees to review inspection reports, draft Standards, provide education, promote the organization, and modernize our processes. Each year, we ask our constituents to let us know if they are willing to serve on one of our committees, and each year we are overwhelmed by your commitment to helping our field, our colleagues, and ultimately the patients we all serve. Please take the time to review the FACT committee charges in this newsletter, and let us know if you are willing to serve on any of them. We hope you will participate in the exciting and important role our committees serve in driving the strategic direction and success of FACT.

Sincerely,

C. Fred LeMaistre, MD

In this Issue:

- Draft 5th Edition Public Comment Period
- Non-HPC Processing Facilities
- Coordinator Commentary
- Quality Corner
- Committee Volunteers Requested
- Reporting Changes to FACT

Editor: Kara Wacker, MBA, RAC

Accreditation Report

Three new blood and marrow transplant programs earned accreditation and fifteen additional organizations received accreditation renewal during the first quarter of 2011. The [complete report of accredited organizations](#) in the first quarter is available at www.factwebsite.org.

Cellular Therapy Programs	Cord Blood Banks
197 Programs Registered	45 Banks Registered
187 Programs Accredited	29 Banks Accredited
10 Applications Pending	16 Applications Pending

Facilities Processing Non-HPC Cellular Therapy Products Encouraged to Pursue FACT Accreditation

It is common knowledge that the [FACT-JACIE Cellular Therapy Standards](#) apply to hematopoietic progenitor cells (HPC), but beginning with the fourth edition they also apply to therapeutic cells (TC) collected from marrow, peripheral blood, umbilical cord, and placental blood collected for therapeutic use other than as HPC. This little-known fact can be important to non-HPC activities for several reasons. FACT accreditation offers the following benefits:

- Provides external validation of the quality of the facility's practices to outside organizations that influence the progress of cellular therapy research, such as funding organizations.
- Demonstrates to clinical trial sponsors that the facility meets or exceeds minimum requirements published by experts in the field of cellular therapy.
- Facilitates the establishment of quality management and process control to minimize liabilities and regulatory noncompliance.

Interest from non-HPC processing facilities is growing, and a small number has already achieved accreditation. Because non-HPC processing is often in support of clinical trials, FACT understands there are unique characteristics of these facilities such as outcome analysis for blinded studies and compliance with Investigational New Drug Applications (INDs) or other regulatory requirements. Such characteristics are compatible with the existing Cellular Therapy Standards, and FACT assigns inspection teams that have knowledge of and experience with non-HPC clinical trials.

We encourage non-HPC processing facilities to [apply for accreditation](#). If you have any questions, please contact the FACT office at fact@unmc.edu.

Your input via the Cellular Therapy for Regenerative Medicine Questionnaire is Requested!

In keeping with its mission to promote quality medical and laboratory practice of cellular therapy and regenerative medicine, the FACT Board of Directors created the Regenerative Medicine Task Force, chaired by Ian McNiece, PhD, to explore how to apply its voluntary accreditation program to new cellular therapies used for the purpose of regenerative medicine. FACT's approach to establishing minimum standards is to partner with experts in the field and to rely on those experts to promote peer-driven quality improvement. As such, the task force is reaching out to the FACT community for information on cellular therapy for regenerative medicine activities.

One of the Regenerative Medicine Task Force's first goals is to determine what cellular products for regenerative medicine are being processed in FACT-accredited processing facilities or in those facilities' larger institutions. Please complete the [Questionnaire Regarding Cellular Therapy Products for Regenerative Medicine](#) to inform us of the types of products your facility and/or your institution are processing for regenerative medicine. You may complete the form for all products at your institution, or complete the survey for products you process and forward this survey to other facilities for completion regarding the products they process. Please submit the questionnaire by May 31, 2011.

As an accredited facility that has already demonstrated its commitment to quality cellular therapy, we appreciate your assistance in identifying cellular therapy for regenerative medicine activities. It is our hope that FACT can assist this field through the improvement of quality and the advancement of cellular therapies for the betterment of patients.

Coordinator Commentary

A Friendly Reminder About Disaster Plans

Sarah Litel-Smith, BSMT(ASCP)

FACT accredited organizations are required to have disaster plans in place. It is acceptable to use institutional plans; however, organizations should consider whether issues specific to the clinical, collection, or processing facilities need to be addressed with supplemental policies and procedures. Areas that may not be addressed in general disaster plans include specific concerns during disasters for the care of immuno-compromised patients, the care of donors during collection, the care of patients during infusions, back-up plans for where donors may be referred during disasters, provisions for cellular therapy products during processing, the use of emergency power, back-up storage, etc. It is important for each organization to consider specific transplant-related issues in case a disaster should occur.

Quality Corner

Innovation and Planning for the Future

Jill Hempel, MS, ASQ-CMQ/OE

As FACT continues its development of the FACTWeb accreditation portal, we have been taking advantage of our constituents' innovative suggestions through several User Feedback Sessions. During these sessions, we are reminded that the organizations we serve also undergo innovative changes to continuously improve their programs and ensure long-term success.

From a quality management perspective, sustained success depends on the organization's ability to continually:

- Use self-assessment and external evaluations to understand future requirements (e.g. properly respond to updated government mandates, new technologies, market conditions, etc.),
- Use innovation to comply with these new requirements that are specific to your organization's mission, vision, and overall goals,
- Ensure your organization responds to new needs and opportunities by changing objectives, targets, and key processes accordingly, and
- Prepare personnel for inevitable changes and updates in a timely manner; any successful change depends on the readiness of the workforce to accept and implement change.

By following these actionable items, the organization has several tools at their disposal to continually innovate and prepare for future changes and developments. FACT hopes to bring this type of innovation to you via FACTWeb in the near future.

The Importance of Notifying FACT of Changes to Your Organization

Today's health care institutions are facing a whirlwind of changes in facilities, organizational structure, services, and personnel. The importance of notifying FACT of changes to your organizations cannot be stressed enough. FACT's policy, [Maintaining Accreditation \(6.2.00.2\)](#), lists changes that accredited organizations are required to report to FACT.

Many people wait to notify FACT of changes until they complete the interim report or apply for renewal accreditation. However, most changes must be reported to FACT within 90 days. Failure to report these changes may risk suspension or termination of your FACT accreditation either due to failure to comply with this requirement or due to a change that does not meet FACT Standards. By reporting changes to FACT as soon as you begin making plans, FACT can assist you throughout the process to ensure that your changes meet the Standards.

FACT Committee Volunteers Requested

The Foundation for the Accreditation of Cellular Therapy has several committees established to help FACT achieve its vision of being the premier organization setting standards and awarding accreditation to programs in the evolving field of cellular therapy.

In light of your experience and important involvement with the FACT accreditation process, we invite you to review the list of committees along with their responsibilities and either nominate yourself or a colleague to serve as a committee member. Individuals who are not currently serving as a FACT inspector but are an active member of one of FACT's parent organizations, ASBMT and ISCT, will be considered as a committee member. **Individuals with cord blood banking experience are especially requested to enhance current committee membership.** Committee chairs will notify final candidates of their appointments.

The committees, along with general descriptions of the committees' charges, are listed below for your consideration. Please indicate which of the committee(s) you would be interested in serving as a member via the [online committee volunteer form](#) by May 31, 2011.

Accreditation Committee *Chair: Phyllis Warkentin, MD*

Review on-site inspection reports in a timely, fair, and consistent manner to make recommendations to the FACT Board of Directors regarding applicant program accreditation status.

Education Committee *Chair: Dennis Gastineau, MD*

Maintain the inspection and accreditation process in order to be thorough, fair, and consistent. Enhance the inspector training program to incorporate continuous quality improvement and ensure the participation of all inspectors.

Standards Committee *Chair: Carolyn Taylor, PhD*

Develop revised core standards and associated guidance materials. Although publication is every three years, the standards development process is ongoing. Address the need for interval or emergency standards. Develop an ongoing dialogue with other cellular/gene therapy organizations to move toward joint standards and accreditation.

Professional Relations Committee *Chair: Catherine Bollard, MD*

Develop a primary objective for relations with each of the following organizations and agencies: ISCT, ASBMT, NetCord, ASFA, NMDP, AABB, CAP, ASHI, and ASGCT.

Quality Management Committee *Chair: Fred LeMaistre, MD*

Monitor developments in treatment outcomes evaluation and reporting. Coordinate with CIBMTR on outcomes measurement and reporting. Educate the BMT community about outcomes evaluation.

Public Relations and Marketing Committee *Chair: Neal Flomenberg, MD*

Enhance visibility of FACT throughout the stem cell transplant community and the cord blood banking industry. Educate constituency about benefits of FACT accreditation including FDA preparedness.

Program Relations Committee *Chair: Jean Sanders, MD*

Establish ongoing communication with accredited transplant organizations and cord blood banks. Effectively use broadcast e-mail and the FACT website to facilitate communications. Survey centers to identify needs of accredited transplant facilities and cord blood banks.

FACTWeb Oversight Committee *Chair: Mark Litzow, MD*

Enhance accreditation process and communications through the development of a web-based system. Eliminate exchange of paper documentation and expedite accreditation process. Evaluate the needs of all users including inspectors, programs, committees, and staff.

ASBMT Presents Lifetime Achievement Award to Richard Champlin, MD

The American Society for Blood and Marrow Transplantation has honored leader, innovator, and educator Richard Champlin, MD, with its Lifetime Achievement Award during the group's annual meeting in February 2011.

The award recognizes Champlin, head of The University of Texas MD Anderson Cancer Center Department of Stem Cell Transplantation and Cellular Biology, for his career-long work developing and improving blood stem cell transplantation as cancer therapy. "Dr. Champlin is a productive and highly accomplished investigator who is an international leader in blood and marrow transplantation," said A. John Barrett, M.D., ASBMT president. "His work has set clinical standards for the field in the United States and beyond. He's an inspirational mentor to trainees and faculty who will carry his teachings forward."

A pioneer in the use of donor stem cell transplants for blood cancers, Champlin was one of the first to recognize that the new blood from the donor actually attacks remaining leukemia or lymphoma cells in the recipient. By studying this graft-vs.-cancer effect, Champlin found that the extremely high doses of chemotherapy given to kill a patient's disease before transplant were unnecessary.

Dr. Champlin served as vice president of FACT's Board of Directors for more than a decade. In this role, he was instrumental in developing FACT standards and its voluntary accreditation program, both of which have been widely adopted by the national and international transplant communities.



*"It is very satisfying to have played a part in the clinical research that has so greatly advanced the standards of care."
Richard Champlin, MD*

Neal Flomenberg, MD Recognized for Contributions to FACT Board of Directors

Neal Flomenberg, MD was recognized in Honolulu, Hawaii for serving eight years on the FACT Board of Directors from 2002 through 2010. Dr. Flomenberg has been an important voice of reason and advice as FACT began its tremendous growth in the past years.

Elizabeth Shpall, MD, Past President of the Board of Directors presented Dr. Flomenberg with a token of the Board's appreciation of his service.



Register for the 17th Annual ISCT Meeting!

Rotterdam, The Netherlands

May 18-21, 2011

FACT Workshop

May 18 (Separate registration required)

FACTWeb User Feedback Session

May 19 (Separate registration required)

Transformation to Online Accreditation

Introducing a NEW Column to Keep You Updated on FACTWeb

Ramona Repaczki-Jones, MSE

The current state of information technology drove FACT, a process-centric organization, to consider the transformation from a paper-based process to an electronic web-based process. This transition was deemed to be critical to FACT's future success. Effectively architecting and automating FACT's current processes within a portal solution provides greater efficiencies and added value to our customers and to the public at large.

For every day that FACT is able to reduce the amount of time to complete an accreditation process, programs can be one day closer to operating at higher standards of quality. The FACTWeb portal solution is a gateway for a website that delivers personalized content to FACT's users in an effective manner.

At the present time, the first phase of FACTWeb implementation has been completed, which includes the redesign of the FACT website. Currently, users can sign up or edit their FACTWeb profile and [log into FACTWeb](#) for personalized content.

The second phase is slated for completion on March 1, 2012. This phase will unveil the online accreditation application and document submission upload process in FACTWeb.

Ramona Repaczki-Jones, FACT's Information Technology Manager, is working with all the FACT accreditation services' stakeholders to ensure the project's success. The FACTWeb project committees are listed below.

- The [FACTWeb Oversight Committee](#), comprised of FACT inspectors and accredited organizations, have an advisory role to the project and report the project's progress to the FACT Board of Directors.
- The FACTWeb Working Group's participants include FACT's accreditation coordinators who are working to streamline the current accreditation processes.
- The FACTWeb Business Group ensures that the overall accreditation portal meets the fiduciary and operational needs of FACT.

If you have any questions or inquiries about the development of FACTWeb, please contact Ramona at factweb@unmc.edu.

FACTWeb User Guide Provides Helpful Information

The [FACTWeb User Guide](#) provides instructions on how to utilize important new features of the redesigned FACT website. This online guide outlines the steps needed to:

- Create a personal profile,
- Update your personal profile,
- Access meeting documents,
- View FACT event history, and
- Manage your organization's staff in FACTWeb.

Organizations Issue Joint Statement in Support of ISBT 128

Several organizations, including FACT, recently released a [joint statement in support of ISBT 128](#), the international coding and labeling standard for cellular therapy products.

The International Cellular Therapy Coding and Labeling Advisory Group, the group creating the ISBT 128 standard for cellular therapy, has been meeting regularly and has established a well structured terminology for hematopoietic progenitor cells. This terminology has been adopted as the formal terminology in the accreditation standards of AABB, FACT, and JACIE. In addition, a number of cellular therapy laboratories have implemented the ISBT 128 Standard for coding and labeling of their products.

We encourage all cellular therapy programs and cord blood banks to begin plans to fully adopt the ISBT 128 technology. Such a requirement has been added to the draft 5th edition FACT-JACIE Cellular Therapy Standards in sections D7 and E7. For more information, consult the draft Standards. Comments regarding this change are welcome.

FACT's Strategic Planning Process Featured in American Society of Association Executives E-Newsletter

The American Society of Association Executives (ASAE) published an online article submitted by Alan K. Leahigh in February 2011 titled, "Implementation of Strategic Plans – How to Make Sure that Yours Is Put Into Action." This article highlights FACT's robust process for implementing its strategic plans.

As the article describes, FACT implements its strategic plan through its committees, and the progress of the committees is presented in a simple, standardized form. Leahigh lists several benefits of this form, concluding with, "The board, committees and staff have an effective, ongoing way to know if progress is being made in accomplishing the goals and objectives in the organization's strategic plan."

FACT is pleased that the ASAE recognizes its ability to put strategic plans into action, and we hope our stakeholders recognize this as well. Congratulations to the FACT Board of Directors and committees!

Observational Study Finds JACIE Accreditation Improves Patient Outcomes

The Journal of Clinical Oncology published a study performed by Gratwohl et. al. on April 11, 2011 titled, "[Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation.](#)"

Results of this observational study found that, "Patient outcome was systematically better when the transplantation center was at a more advanced phase of JACIE accreditation, independent of year of transplantation and other risk factors."

The authors concluded that implementation of a comprehensive clinical quality management system improves patient outcomes.

FDA Releases Final Guidance for Industry: Cellular Therapy for Cardiac Disease

The FDA released "[Final Guidance for Industry, Cellular Therapy for Cardiac Disease](#)" to provide sponsors with recommendations on the design of preclinical and clinical studies, and on the chemistry, manufacturing, and controls (CMC) information to include in an Investigational New Drug application (IND) for cellular therapy for cardiac disease. This guidance also provides recommendations regarding the information that should be submitted regarding the product's delivery system. This guidance finalizes the draft guidance entitled "Guidance for Industry: Somatic Cell Therapy for Cardiac Disease" dated March 2009.

Three 2011 FACT Workshops are Open for Registration!

May 18, 2011

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the ISCT Annual Meeting in Rotterdam, The Netherlands
Held in collaboration with JACIE, this workshop will include a FACT track and a JACIE track during which the respective organizations will provide information regarding their inspection and accreditation processes. Everyone will join in the afternoon for the Standards track, including interactive exercises and practical application of the requirements.

May 31, 2011

Cellular Therapy Collection Inspection Workshop

in conjunction with the ASFA Annual Meeting in Scottsdale, Arizona
This training workshop is designed to explain the requirements for FACT accreditation of cellular therapy collection facilities. Practical application of FACT requirements stimulates discussion about effective and ineffective inspection practices and preparation techniques. Focus will be on collection facility requirements, with an overview of clinical and processing requirements.

June 26, 2011

Cord Blood Inspection and Accreditation Workshop

in conjunction with the International Umbilical Cord Blood Transplantation Symposium in San Francisco, California
This training workshop is designed to explain the requirements for FACT-NetCord accreditation of cord blood banks. FACT representatives will be in attendance to clarify the intent of the Cord Blood Standards, provide inspectors tips for conducting inspections, and assist banks in organizing and preparing their banks for the accreditation process.

Save the date for the following workshops:

September 2011

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the ISCT North America Regional Meeting in Charlottesville, Virginia

October 2011

Cord Blood Inspection and Accreditation Workshop

in conjunction with the World Cord Blood Congress in Rome, Italy

**[View the FACT Workshop and Webinar Calendar
for More Educational Opportunities!](#)**

Congratulations to our new cellular therapy inspectors!

Brenda Letcher, RT(CSMLS)
Canadian Blood Services - Edmonton

Doris Quinn, BS, RN
Canadian Blood Services - Edmonton