

Current Committee Opportunities

Common Standards Steering Committee

Purpose: Develop and revise Standards and guidance for the fourth edition *FACT Common Standards for Cellular Therapies* using evidence-based science and considering evolving uses of cellular therapy. The Common Standards represent the basic fundamentals of cellular therapy that can be applied to any cell source or therapeutic application and are intended to be used throughout product development and clinical trials.

Responsibilities:

- Attend weekly, bi-weekly, or monthly virtual meetings during the drafting phase and public comment review phase.
- Draft Standards and Accreditation Manual for cellular therapy product collection, processing, and administration.
- Evaluate public comments and approve or disapprove as appropriate.
- Draft and propose interim standards and guidance updates, as necessary.
- Term is approximately three years beginning at the initiation of a new edition of Standards and ending at the initiation of the subsequent edition of Standards (next term May 2025 - June 2027).

Specific expertise requested:

- Experience in cellular transplantation (clinical, collection, or processing), immune effector cellular therapies, and quality.
- Expertise in Rheumatology, Cardiology, or Surgical (TILs) is preferred.

Cord Blood Standards Steering Committee and Sub-Committees

Purpose: Develop and revise Standards and guidance for the ninth edition *FACT Cord Blood Standards* using evidence-based science and considering evolving uses of cellular therapy.

Responsibilities:

- Attend weekly, bi-weekly, or monthly virtual meetings during the drafting phase and public comment review phase.
- Draft Standards and Accreditation Manual for product collection, processing, and administration.
- Evaluate public comments and approve or disapprove as appropriate.
- Draft and propose interim standards and guidance updates, as necessary.
- Term is approximately three years beginning at the initiation of a new edition of Standards and ending at the initiation of the subsequent edition of Standards (next term September 2025 - October 2027).

Specific expertise requested:

- Experience in cord blood banking (banking quality management and operations, donor management and collection, processing, and management of storage, listing, distribution, and release of units).

Cellular Therapy Accreditation Committee

Purpose: Review cellular therapy program and facility inspection reports in a timely, fair, and consistent manner, provides recommendations to the FACT Board of Directors regarding applicant program or facility accreditation status, and maintains oversight of the accreditation process.

Responsibilities:

- Attend monthly 1.5 hour virtual meeting.
- Review and assess inspection and accreditation reports.
- Determine next steps for applicant organizations to achieve accreditation.
- Review organizational survey results for streamlining the accreditation process.

Specific expertise requested:

- Experience in all areas of accreditation (clinical, apheresis, with priority for cell processing with more than minimal manipulation).
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Cord Blood Accreditation Committee

Purpose: Review cord blood bank inspection reports in a timely, fair, and consistent manner, provides recommendations to the FACT Board of Directors regarding applicant cord blood bank accreditation status, and maintains oversight of the cord blood bank accreditation process.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Review and assess inspection and accreditation reports.
- Determine next steps for applicant cord blood banks to achieve accreditation.

Specific expertise requested:

- Experience with cord blood banking and collection.
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Inspector Development Committee

Purpose: Promote the highest level of excellence and consistency in inspections and ensure an adequate core of committed inspectors.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Develop strategies for recruitment, selection, training, retention, and performance of volunteer inspectors.
- Develop curriculum, annual requirements, and administer online inspector continuing education.

Specific expertise requested:

- Experience as an inspector (clinical, apheresis collection, cell processing, cord blood banking).
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Education Committee

Purpose: Develop education and training programs for volunteer inspectors and personnel at applicant and accredited facilities to promote knowledge and understanding of current standards, create awareness of commonly cited deficiencies, and promote quality in cellular therapy. The committee and its staff serve as a resource for other FACT committees that have constituent education needs.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Develop content for accreditation workshops and webinars.
- Develop content for inspector training.
- Assess and evaluate the quality of FACT's educational programs and recommend improvements.
- Serve as a FACT presenter for in-person and online education events.
- Serve as a resource for other FACT committees that have constituent education needs.

Specific expertise requested:

- Experience in clinical transplant, apheresis collection, cell processing, and cord blood banking.
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Quality Management Committee

Purpose: Develop and administer programs that maintain high quality in accredited programs.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Develop and review material for the FACT Quality Management Handbook.
- Offer a comprehensive schedule of webinars related to quality management activities.
- Develop content for Quality Boot Camps.
- Develop quality metrics for FACT inspection and accreditation processes, including effectiveness, efficiency, and customer satisfaction.

Specific expertise requested:

- Experience with quality management and the FACT inspection process.
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FACT – CIBMTR Data Audit Committee

Purpose: Coordinate the evaluation of transplant and cellular therapy data audits performed by FACT and CIBMTR.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Participate in the joint FACT-CIBMTR data review process by assessing program's progress on implementing corrective action plans.
- Develop education and provide assistance to programs to improve data management and reporting.

Specific expertise requested:

- Experience with clinical and data management, including physicians and data managers.

Immune Effector Cell Task Force

Purpose: Develop and promote standards and accreditation for immune effector cellular therapy.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Evaluate current and evolving immune effector cellular therapy practices and propose standards as appropriate.
- Identify opportunities and barriers for advancing immune effector cellular therapy and methods in which FACT can contribute to solutions.
- Develop and present educational content for a variety of stakeholders, including, but not limited to, immune effector cellular therapy programs, solid tumor oncologists, industry, payers, and multistakeholder groups.

Specific expertise requested:

- Experience with tumor infiltrating lymphocytes (TIL), specifying area of experience (starting material collection, cellular product processing, or clinical administration).
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Clinical Outcomes Improvement Committee

Purpose: Assist hematopoietic progenitor cell transplant programs with improving patient outcomes by providing resources, creating tools, and reviewing corrective action plans.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Review corrective action plans from programs that did not meet or exceed expected clinical outcomes.
- Propose potential standards and guidance information to the Standards Committee when appropriate based on reviews of clinical outcomes corrective action plans.
- Provide Education Committee with recommendations for educational sessions regarding available comparative national and international data and their significance.
- Educate cellular therapy programs about how to develop an effective corrective action plan including methods for conducting a root-cause investigation and analysis.

Specific expertise requested:

- Experience with clinical outcomes assessment and corrective action plans.
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Histocompatibility Committee

Purpose: Develop guidelines for the minimum criteria for Histocompatibility Typing Standards and Accreditation Organizations and evaluates those organizations seeking to be recognized by FACT against the accepted criteria.

Responsibilities:

- Attend monthly one-hour virtual meeting.
- Propose potential guidelines with minimum criteria to the Accreditation Committees for accepting accreditation of histocompatibility testing and services from accrediting organizations.
- Evaluate accrediting organizations seeking to be recognized by FACT against established criteria.
- Review established histocompatibility guidelines for ongoing appropriateness with each edition of the FACT – JACIE Hematopoietic Cellular Therapy Standards.
- Propose potential modifications to the Standards Committees when appropriate based on evaluations of histocompatibility testing organizations.

Specific expertise requested:

- Experience with histocompatibility testing and services.
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