FACT
(Foundation for the Accreditation of Cellular Therapy):
An Inspector’s View

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Standards

FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration

Objective: promote quality medical and laboratory practice in hematopoietic progenitor cell (HPC) transplantation and other therapies using cellular products.
Standards

• Apply to HPC from any source
• Apply to Therapeutic Cells from any source for use other than as HPC
• Apply to all phases of collection, processing, storage and administration of cells from marrow or peripheral blood
• Apply to administration of the cellular product from umbilical and/or cord blood, applying clinical standards
Standards

• Do not apply to the collection, processing, or banking of umbilical cold and placental blood cells

• See NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release
Standards

• Minimal performance guidelines

• More rigorous internal requirements acceptable
History of Standards

• FACT founded 1996 (ASBMT and ISCT)
• 1<sup>st</sup> Edition of Standards 1996
• Inspection and Accreditation Program in North America 1997
• Joint Accreditation Committee of ISCT and EBMT (JACIE) 1999
• 2<sup>nd</sup> Edition of Standards 2002 (joint review by FACT and JACIE)
• 3<sup>rd</sup> Edition of Standards 2006
• 4<sup>th</sup> Edition of Standards available, effective 1/29/09
Structure of Standards

• Similar standards for the Clinical Program, Collection Facility and Processing Facility


• 3rd Edition incorporated regulatory requirement for donor screening, donor testing, and eligibility determination, labeling, and cGMP as published by the U.S. FDA
Accreditation

• Basis for FACT or JACIE Accreditation is documented compliance with the current edition of the Standards

• FACT and JACIE maintain separate and parallel accreditation processes

• Determined by evaluation of the written information provided by the applicant facility and by on-site inspection
Accreditation

• Various combinations of Clinical Transplantation Program, Collection Facility and Cell Processing Laboratory

• Accreditation cycle is 3 years

• Accredited facilities must complete an Annual Report Form for each year between inspections
Written Information Submitted by Program(s)

• Program Documentation
  FACT checklists, org chart, floor plans, locations, FDA registration
• Clinical Program Documentation
• Cellular Therapy Product Collection Facilities Documentation
• Cellular Therapy Product Processing Facility Documentation
FACT Office Personnel

• Review materials submitted

• Request additional materials or clarification of those sent

• Once all materials have been received and reviewed, a date for on-site inspection is agreed upon
Prior to On-Site Inspection

• Team assembled by FACT office
• Materials sent to each inspector
• Read letter of instruction from FACT office
• Read info provided by facility
• Request missing documentation
Inspectors

- Qualified by training and experience in HPC
- Affiliated with accredited or applicant facility
- Attended inspector training
- Working knowledge of Standards
On-Site Inspection

• Initial interview

• Inspection

• Exit interview
After the Inspection

• Prepare and send report to Team Leader within 3 days of completing the inspection
• Team Leader compiles the final report
• Final report is reviewed and presented to FACT Accreditation Committee ~ 4-8 weeks after inspection
• Letter to facilities with deficiencies and/or variances to be addressed
Full Accreditation

Chair of the Accreditation Program will determine adequacy of:

- Written documentation of correction of all deficiencies
- Response to all variances
- Chair may award full accreditation
- Incomplete or unsatisfactory responses may be referred back to Committee
Inspection - Getting There
Questions

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