Collection Section

6th EDITION OF FACT-JACIE STANDARDS

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Clinical	Collection Marrow	Collection Apheresis	Processing
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Marrow Collection Facility	C2 Apheresis Collection Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	CM4 Quality Management	C4 Quality Management	D4 Quality Management
B5 Policies and Procedures	CM5 Policies and Procedures	C5 Policies and Procedures	D5 Policies and Procedures
B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management	CM6 Allogeneic and Autologous Donor Evaluation and Management	C6 Allogeneic and Autologous Donor Evaluation and Management	D6 Equipment, Supplies, and Reagents
B7 Recipient Care	CM7 Coding and Labeling of Cellular Therapy Products	C7 Coding and Labeling of Cellular Therapy Products	D7 Coding and Labeling of Cellular Therapy Products
B8 Clinical Research	CM8 Process Controls	C8 Process Controls	D8 Process Controls
B9 Data Management	CM9 Cellular Therapy Product Storage	C9 Cellular Therapy Product Storage	D9 Cellular Therapy Product Storage
	CM10 Cellular Therapy Product Transportation and Shipping	C10 Cellular Therapy Product Transportation and Shipping	D10 Cellular Therapy Product Transportation and Shipping
			D11 Distribution and Receipt
			D12 Disposal
B10 Records	CM11 Records	C11 Records	D13 Records
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	

Changes in collection standards: from 5th to 6th (current) version

- Standards were changed : 18
- Standards were reworded (minor changes) : 10
- **New Standards : 18**

PART CM

New in 6th edition

- CM2.3.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

PART CM

New in 6th edition

- CM5.1.5 Prevention of mix-ups and cross-contamination.
- CM5.1.12 Hygiene and use of personal protective attire.
- CM5.1.13 Emergency and disaster plan *related to the marrow collection procedure.*

- *CM5.7* Variances shall be pre-approved by the Marrow Collection Facility Medical Director, and reviewed by the Quality Manager

PART CM

New in 6th edition

- CM6.3.5 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- CM6.3.6 There shall be a written order from a physician specifying, at a minimum, *timing* and goals of collection.
- CM7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."
- CM8.15.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

- ***Qualification:*** The establishment of confidence that equipment, supplies, and reagents function *consistently within established limits.*

- ***Validation*****:** Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a *cellular therapy product meeting its predetermined specifications*.

PART C

New in 6th edition

- C4.13.1 Qualification plans shall be reviewed and approved by the Apheresis Collection Facility Director or designee.
- C4.14.2 Each validation shall include:
  - C4.14.2.1 An approved validation plan, including conditions to be validated.
  - C4.14.2.2 Acceptance criteria.
  - C4.14.2.3 Data collection.
  - C4.14.2.4 Evaluation of data.
  - C4.14.2.5 Summary of results.
  - C4.14.2.6 Review and approval of the validation plan, results, and conclusion by the Apheresis Collection Facility Director or designee and the Quality Manager or designee.

PART C

New in 6th edition

- C5.1.5 SOP for administration of blood products.
- C8.3.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. *Where no traceable standard is available, the basis for calibration shall be described and documented*.

PART C

New in 6th edition

- C5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.
- C5.4 ~~Copies of~~ Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.

PART C

New in 6th edition

- C4.14.3 Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be *validated* or verified as appropriate.

PART CM and C

New in 6th edition

BACKUP COVERAGE OF STAFF (CM3.3.2, C3.4.1,)

- (Facilities were often found to have minimal staff that was only sufficient should no staff members be absent.)
- The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one *designated* trained individual with an identified trained backup to maintain sufficient coverage.

Apheresis Collection

C2: Apheresis Collection Facility

- C2.1 There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.
- C2.1.1 The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.
- C2.1.2 There shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination **in outpatient units where collection is performed**.

C2: Apheresis Collection Facility

- C2.4 Critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, *sterility*, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.
  - C.2.4.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

C2: Apheresis Collection Director

- C3.1 Apheresis Collection Facility Director

  C3.1.1 There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the Apheresis Collection Facility. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.

- C3.2 Apheresis collection Facility Medical Director

  C3.1.1There shall be an Apheresis Collection Facility Medical Director who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation.

C2: Apheresis Collection Director

- C3.1 Apheresis Collection Facility Director
- C3.2 Apheresis Collection Facility Medical Director
- Shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months *preceding accreditation* and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the *accreditation cycle*.
- Shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
  - Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.

C2: Apheresis

Quality Manager

C3.3.1 There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Apheresis Collection Facility.

C3.3.2 The Apheresis Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.

C3.3.2.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

C2: Apheresis Collection

Before collection

C6.2.9 Documentation of consent shall be available to the Apheresis Collection Facility staff prior to the collection procedure.

6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

C2: Apheresis Collection

Before collection

C6.3.7 Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.

C6.3.8 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. *Collection staff shall document review of these issues prior to collection*.

C2: Apheresis Collection

Before collection

C8.10 If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure.

C8.10.1 Adequacy of central line placement shall be verified by the Apheresis Collection Facility *prior to initiating the collection procedure.*

C2: Apheresis Collection

Before collection

C8.9 There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a **qualified** person *immediately prior to each collection procedure.*

C2: Apheresis Collection

At the time of collection

C8.7 Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.

C2: Apheresis Collection

At the time of collection

C8.7 A complete blood count, including platelet count, shall be performed within 24 hours prior to each *subsequent* cellular therapy product collection by apheresis.

C8.8 There shall be peripheral *blood count criteria* to proceed with collection.

C2: Apheresis Collection

At the time of collection

C8.5 Autologous and/or CMV-appropriate and *irradiated* blood components shall be available during the apheresis collection procedure for all donors.

C8.6 Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, *timing* and goals of collection.

C2: Apheresis Collection

During collection

C7.4 LABEL CONTENT

C7.4.1 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix

C7.4.3 Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.

C2: Apheresis Collection

At the time of collection

C7.1 ISBT 128 CODING AND LABELING

C7.1.1 Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.

C7.1.2 If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.

C2: Apheresis Collection

During collection

C8.13 Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.

C8.16 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.

C8.16.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

C2: Apheresis Collection

After collection

C8.15 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.

C9.2 Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

C10.2 *The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.*

C10.3 The cellular therapy product shall be transported and/or shipped to the Processing Facility in a *validated* container at a temperature defined in a Standard Operating Procedure.

C2: Apheresis Collection

After collection

C10.3.2 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

Shipping: The physical act of transferring a cellular therapy product within or between facilities. During shipping the product *leaves the control of trained personnel* at the distributing or receiving facility.

Transport: The physical act of transferring a cellular therapy product within or between facilities. During transportation the product *does not leave the control of trained personnel* at the transporting or receiving facility.

JACIE joint accreditation committee ISCT EBMT European Society for Blood and Marrow Transplantation International Society for Cellular Therapy

PART C

ECP

Extracorporeal Photopheresis

C8.17 There shall be a policy addressing safe administration of ECP.

C8.17.1 Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe administration of ECP.

PART C

ECP

Extracorporeal Photopheresis

C8.17.2 The ECP procedure shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.

C8.17.3 A final report of the details of ECP administered shall be documented in the patient's medical record.

Labels

CELLULAR THERAPY PRODUCT LABELING

6th	6th	6th	6th	6th	5th	5th	5th	5th	5th
Element	Partial label	Label at compl etion of collec tion	Label at compl etion of proce ssing	Label at distri b ution for admi n istrati on	Element	Partial label	Label at compl etion of collec tion	Label at compl etion of proce ssing	Label at distri b ution for admi n istrati on
Unique numeric or alphanumeric identifier	AF	AF	AF	AF	Unique numeric or alphanumericidentifi er	AF	AF	AF	AF
Proper name of product	AF	AF	AF	AF	Proper name of product	AF	AF	AF	AF
Product attributes			AC	AC	Product modifiers	AF		AF	AF
					Product attributes (manipulations)			AC	AC
Recipient name and/or identifier		AT	AT	AT	Recipient nameand identifier (if applicable)	AF	AT	AT	AT
Identity and address of collection facility or donor registry		AT	AC	AC	Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC	Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT	Approximate volume		AT	AT	AT
Name and quantity of anticoagulant and other additives		AC	AC	AC	Name and volume or concentration of anticoagulant and other additives		AT	AT	AT

CELLULAR THERAPY PRODUCT LABELING

6th edition					5th edition				
Donor identifier and (if applicable) name		AT	AT	AT	Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature range		AT	AT	AT	Recommended storage temperature range		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see CM7.4.2, C7.4.2, D7.4.2).		AT	AT	AT	Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4).		AT	AT	AT
As applicable:					If applicable:				
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT	Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT	Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT	Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT
Identity and address of processing and distribution facility(ies)			AC	AC	Identity and address of processing and distribution facility(ies)			AC	AC
Statement "Do Not Irradiate"			AT	AT	Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AC	AC	Expiration Date (if applicable)			AT	AT
Expiration Time (if applicable)			AC	AC	Expiration Time (if applicable)			AC	AT
ABO and Rh of donor (if applicable)			AC	AC	ABO and Rh of donor (if applicable)			AC	AC

CELLULAR THERAPY PRODUCT LABELING

6th edition					5th edition				
RBC compatibility determination (if applicable)				AC	RBC compatibility testing results (if applicable)				AC
					Statement "Properly Identify Intended Recipient and Product"				AT
Statement indicating that leukoreduction filters shall not be used.				AT	Statement indicating that leukoreduction filters should not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT	Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
					Statement "For Use By Intended Recipient Only" (if for allogeneic recipient)				AT
					Statement "For Nonclinical Use Only" (if applicable)				AT
Date of distribution				AC	Date of distribution				AC

CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING AND TRANSPORT ON PUBLIC ROADS

6th edition					5th edition		
Element	Inner container document	Outer container label			Element	Inner container document	Outer container label
Date of distribution	AC	AC			Date of distribution and time, if appropriate	AC	AF
Time of distribution, if appropriate	AC	AC					

Removed standards

5th edition Standards not included in the 6th edition

PART CM: TESTING

REMOVED

- CM6.3.9 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- CM6.3.10 A red cell antibody screen shall be performed on allogeneic recipients.
- CM7.3.2 Marrow Collection Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the cellular therapy product.

PART C:

REMOVED

- C4.3.3 A description of minimal trainer qualifications and a uniform plan for staff training.
- C4.4 The Quality Management Plan shall include, or summarize and reference, policies and procedures for development, approval, validation, implementation, review, revision, and archival for all critical processes, policies, and procedures

PART C:

REMOVED

- C4.10.1.7 Follow-up for effectiveness of corrective action.
- C4.10.5 Deviations from Standard Operating Procedures shall be documented.
- C4.10.5.2 Unplanned deviations and associated corrective actions shall be reviewed by the Apheresis Collection Facility Director or designee.
- C4.10.6 There shall be a defined process improvement plan that includes policies or procedures for the recognition and investigation of the cause of all issues that require corrective action.

PART C:

REMOVED

- C5.1.3 Donor treatment.
- C5.1.16 Facility management and monitoring.
- C6.4.1 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- C6.4.2 A red cell antibody screen shall be performed on allogeneic recipients.
- C7.3.2 Apheresis Collection Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the cellular therapy product.
- C11.1.2.1 If records are maintained in more than one location, there shall be a system to ensure prompt identification, location, and retrieval of all records.

FACT-JACIE 6th Edition

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Thank you very much for your attention!