Collection Section

6th edition of FACT-JACIE Standards

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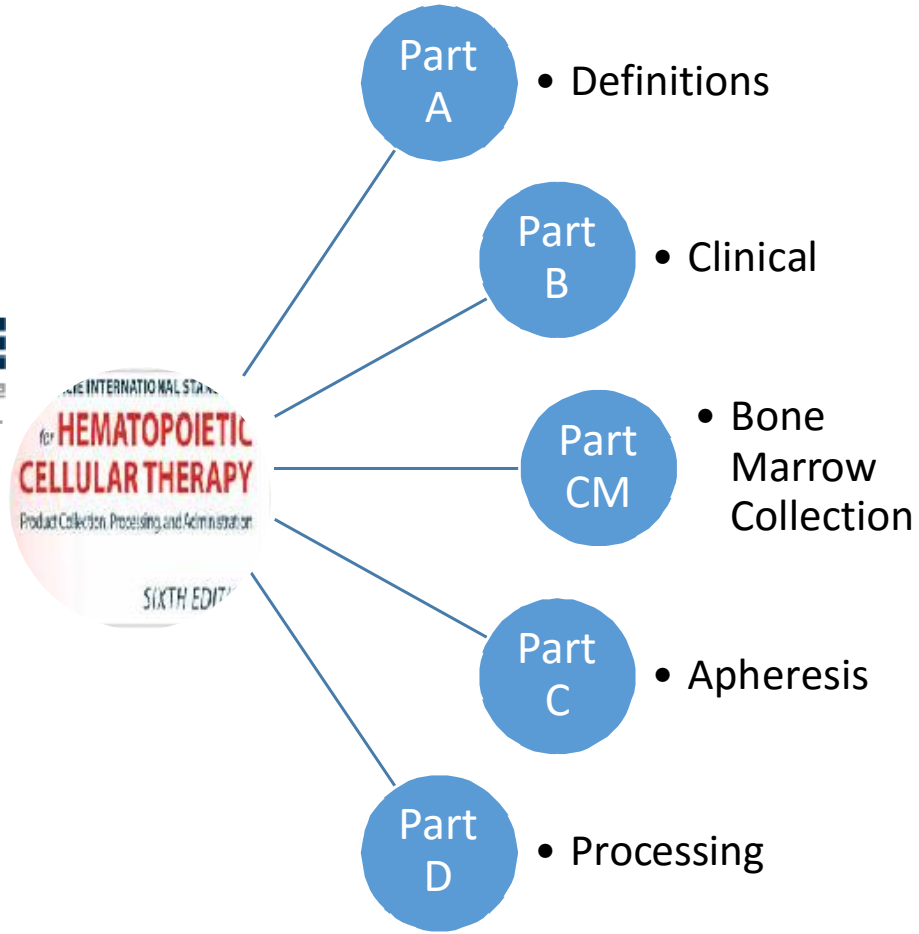
FACT-JACIE Standards



PART CM

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

- *CM5.1.5 Prevention of mix-ups and cross-contamination.*

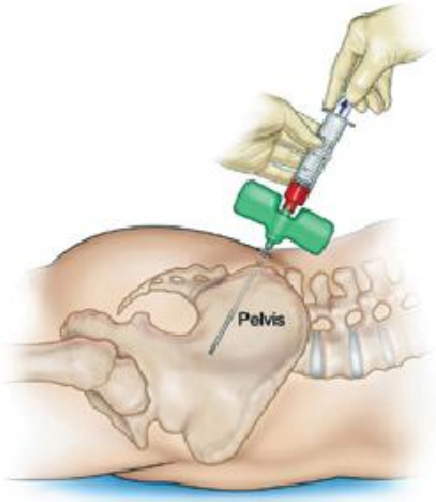
- *CM5.1.12 Hygiene and use of personal protective attire.*

- *CM5.1.13 Emergency and disaster plan related to the marrow collection procedure.*

PART CM

- *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.*

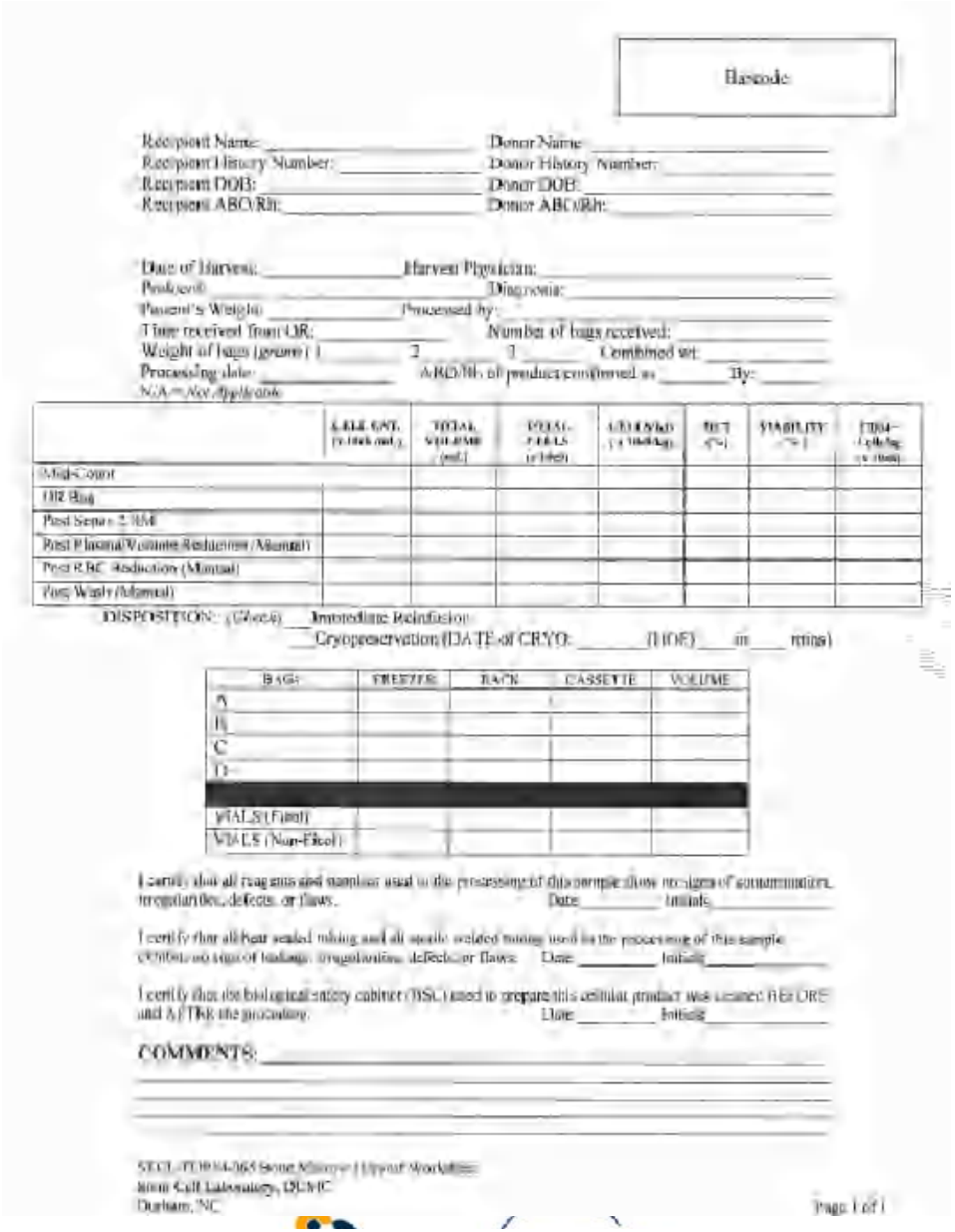
- *CM6.3.6 There shall be a written order from a physician specifying, at a minimum, timing and goals of collection.*



Part CM

- *CM7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labelled 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.*



Barcode

Recipient Name: _____ Donor Name: _____
Recipient History Number: _____ Donor History Number: _____
Recipient DOB: _____ Donor DOB: _____
Recipient ABO/Rh: _____ Donor ABO/Rh: _____

Date of Harvest: _____ Harvest Physician: _____
Product: _____ Diagnosis: _____
Patient's Weight: _____ Processed by: _____
Time received from OR: _____ Number of bags received: _____
Weight of bags (grams): 1 _____ 2 _____ 3 _____ Combined wt: _____
Processing date: _____ ABO/Rh of product confirmed as _____ By: _____
N/A = Not Applicable

Mnl Count							
Hct Bag							
Post Spun CBMC							
Post Plasma/Volume Reduction (Manual)							
Post RBC Reduction (Manual)							
Post Wash (Manual)							

DISPOSITION: (Check) ___Immediate Reinfusion
___Cryopreservation (DATE of CRYO: _____ (TIME) _____ in _____ rating)

BAG	FREEZER	RACK	CASSETTE	VOLUME
A				
B				
C				
D				
VIALS (Final)				
VIALS (Non-Final)				

I certify that all reagents and materials used in the processing of this sample show no signs of contamination, irregularities, defects, or flaws. Date _____ Initials _____

I certify that all heat sealed tubing and all sterile related tubing used in the processing of this sample contains no signs of leakage, irregularities, defects or flaws. Date _____ Initials _____

I certify that the biological safety cabinet (BSC) used to prepare this cellular product was cleaned BEFORE and AFTER the procedure. Date _____ Initials _____

COMMENTS: _____

STCL-FORM-065 Bone Marrow Harvest Worksheet
Stem Cell Laboratory, DUMC
Durham, NC

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http://spitfire.emmes.com/study/duke/SOP/Forms/STCL-FORM-065%20Bone%20Marrow%20Harvest%20Worksheet.pdf

PART C

- *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

- *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

- *C5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.*

- *C5.4 Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.*

PART C

- *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

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.*

C3: Personnel
Apheresis Collection Facility 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: Personnel
Apheresis Collection Facility Medical Director

- *C3.2.1There shall be an Apheresis Collection Facility Medical Director who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation*

- *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.*

C3: Personnel
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.

C6: Allogeneic and Autologous Donor Evaluation and Management

Apheresis Collection - Before collection

C6.2.9

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

C6.3.6

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

C6: Allogeneic and Autologous Donor Evaluation and Management

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.

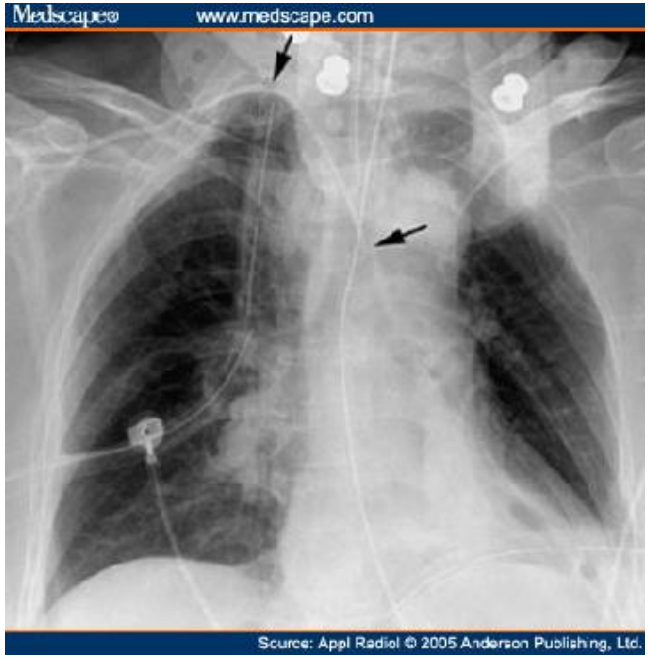
C8: Process Controls

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.



C8: Process Controls

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.

C8: Process Controls

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.

C8: Process Controls

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.

C8: Process Controls

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.

FORM FRM5071/2 Effective: 23/03/15

Request to Collect and Process Stem Cell and Immunotherapy Products

Both sections must be completed. If the required information to complete section two is not available section one can be completed and the form sent by secure email to your local NHSBT Stem Cell Immunotherapy Department and Therapeutic Apheresis Services Department (if required) to reserve collection/processing dates. Section two must be completed as soon as the required information is available. The complete form must be sent to your local NHSBT SCI laboratory **before** donor mobilisation or patient conditioning starts. Please see INF1243 for additional information.

SECTION ONE – Essential information required to reserve collection and processing dates

Transplant type: Please select...
Transplant Consultant:

Donor Type: Please select...

RECIPIENT:
Last name:
First name:
NHS number:
Hospital No.:
Date of birth (dd:mm:yy):
Gender: Please select...

DONOR: Panel ID:
Last name:
First name:
NHS number:
Hospital No.:
Date of birth (dd:mm:yy):
Gender: Please select...

Diagnosis (Broad): Please Select
Diagnosis (Specific):

SECTION TWO – Essential information required before mobilisation/conditioning has commenced

COLLECTION DETAILS

Target CD34 dose (x10^6/kg):
Target DLI dose if applicable (x10^6/kg):
Recipient weight for dose calculations (Kg):
Infectious Disease Markers completed within 30 days of collection date: Please select...
Additional Information: Please provide additional donor information ie weight of small adult or paediatric donors, or any known disease transmission risks.

PROCESSING OPTIONS – Please indicate intended processing requirements

Cryopreserve cells: Please select...
Bone marrow processing: Please select...
Fresh DLI (state dose x10^6/kg):
Enrichment/depletion: Please select..
Cryopreserve DLIs: No
State start dose for half log increments: Please select
Other DLI Dose Range
Additional Information: Please provide additional processing information, eg ABO-reactive antibody titres

TRANSPLANT INFORMATION

Recipient blood group: Please select..
Donor blood group: Please select...
Fresh Cells (max CD34 dose – x10^6/Kg):
Fresh Cells (max CD3 dose – x10^6/Kg):
Transplant hospital/ward:
Transplant date (dd:mm:yy):
Person completing Section Two:
Date completed (dd:mm:yy):

(Template Version 01/11/13)

Cross-Referenced in Primary Document: INF1243 Page 1 of 1

Collection order form

http://hospital.blood.co.uk/patient-services/stem-cells/collection-of-stem-cells-by-apheresis/#top

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

C7: Coding and Labelling of cellular therapy products

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.

C7: Coding and Labelling of cellular therapy products

C7.1 ISBT 128 CODING AND LABELING

ISBT 128
ICCBBA is a nongovernmental organization in official relations with the World Health Organization

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.

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

C8: Process Controls
- 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.

C8: Process Controls
- 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.

C10:Cellular therapy product transportation and shipping

C10.3.2

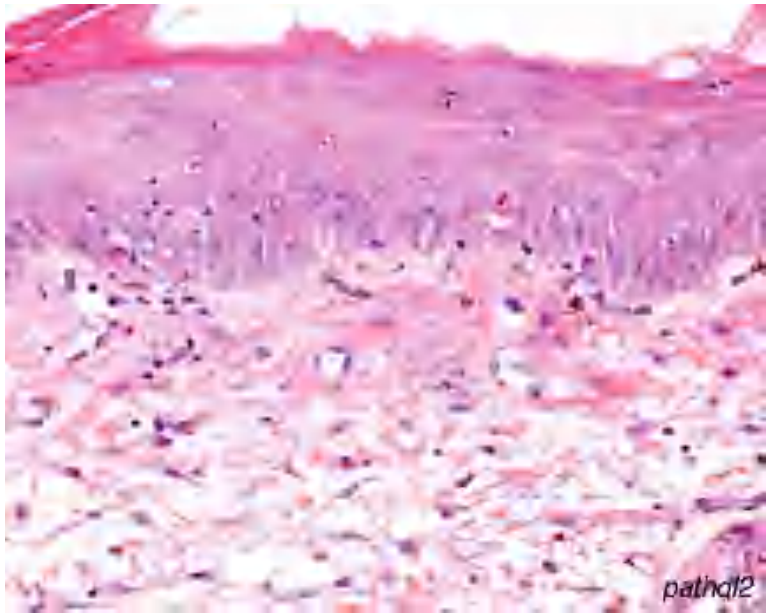
If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

C10.3.2 ~~If the intended recipient has received high-dose therapy,~~ the cellular therapy product shall be transported by a qualified courier to the Processing Facility.

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.

PART C - ECP



Extracorporeal Photopheresis

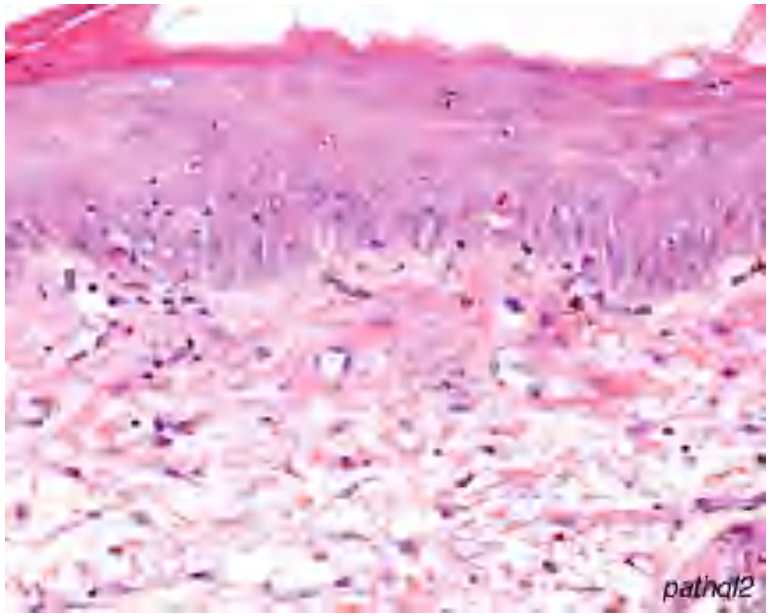
C8.17

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.