JACIE collection standards 7th edition

PARTS

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- TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS

B

- CLINICAL PROGRAM STANDARDS

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D

- PROCESSING FACILITY STANDARDS

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Definition

- Donor: A person who is the source of cells or tissue for a cellular therapy product.
- The term “donor” is used by the Standards even in the autologous setting because considerations for informed consent and suitability (i.e. safety) of the individual include issues above and beyond the individual’s status as a transplant patient.

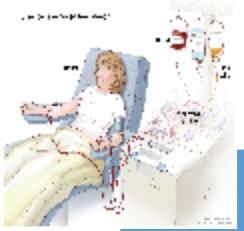
Allogeneic and autologous donor evaluation and management

PART B: CLINICAL PROGRAM STANDARDS

- B6.1 There shall be written criteria for allogeneic and autologous donor **selection**, evaluation, and management by trained medical personnel.

PART CM: MARROW COLLECTION FACILITY STANDARDS

- CM6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.



PART C: APHERESIS COLLECTION FACILITY STANDARDS

- C6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.

B6: Allogeneic **and** autologous donor selection, evaluation, and management

- Standards are intended to promote the safety of the donor and recipient as well as the safety and efficacy of the cellular therapy product.
- For allogeneic donors, **all** the requirements in B6 apply, including standards to safeguard appropriate confidentiality, confirm histocompatibility matching, and help protect the recipient from the risks of transmissible disease.
- For autologous-only Clinical Programs, **many, but not all**, of the requirements in this section apply. The standards and substandards under B/CM/C6.1, B6.2, and B6.3 apply to autologous transplantation except for those that specify allogeneic donors only.

B6: Allogeneic **and** autologous donor selection, evaluation, and management

Selection criteria to include:

Criteria for the selection of allogeneic donors who are **minors or elderly**.

Criteria for the selection of allogeneic donors when **more than one donor** is available and suitable.

Information regarding the donation process should be provided to the potential allogeneic donor **prior** to HLA typing

B/CM/C 6.1 There shall be **written** criteria for allogeneic and autologous donor selection*, evaluation, and management by trained medical personnel.

How to check if standard is met:

- The inspector may ask to **verify** compliance with donor selection SOPs by **reviewing** a specific donor evaluation.
- Review Autologous patient notes (available for MED-A audit)
- If the program performs both allogeneic and autologous transplants, then the criteria for both types of transplant must be written
  - If a program performs only autologous transplants, then the written criteria need only reflect autologous donors
  - If a Clinical Program only performs allogeneic transplants, then the written criteria need only pertain to allogeneic donors

*PART B only: CLINICAL PROGRAM STANDARDS

Donor rights

- Opportunity to ask questions and receive full information
- Right to refuse to donate and be informed of the potential consequences to recipient of such refusal

- The understanding of „full information" varies – some center might try to use general forms for medical procedures – some use forms developed for donors only

Allogeneic and Autologous Donor information and consent to donate

Apheresis, blah, drugs, blah, safety, blah, process… Hey, don't worry, I'm a doctor

Allogeneic and Autologous Donor information and consent to donate

Here's a description of the process including the risks. Please take some time to read and feel free to ask questions

Minimum donor information

Risks /benefits of procedure

Tests and procedures performed on donor

Rights to review the results

Alternative collection methods

Protection of medical information and confidentiality

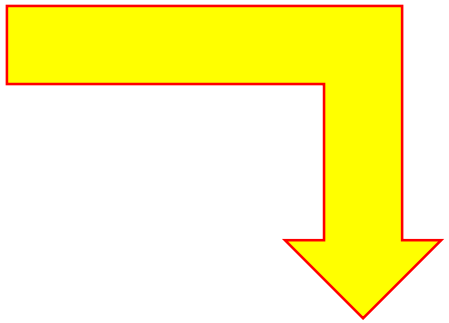
Storage & discard policy

IN TERMS THE DONOR CAN UNDERSTAND

Consent

The donor shall have the right to

1. **refuse** to donate
2. **withdraw consent**.



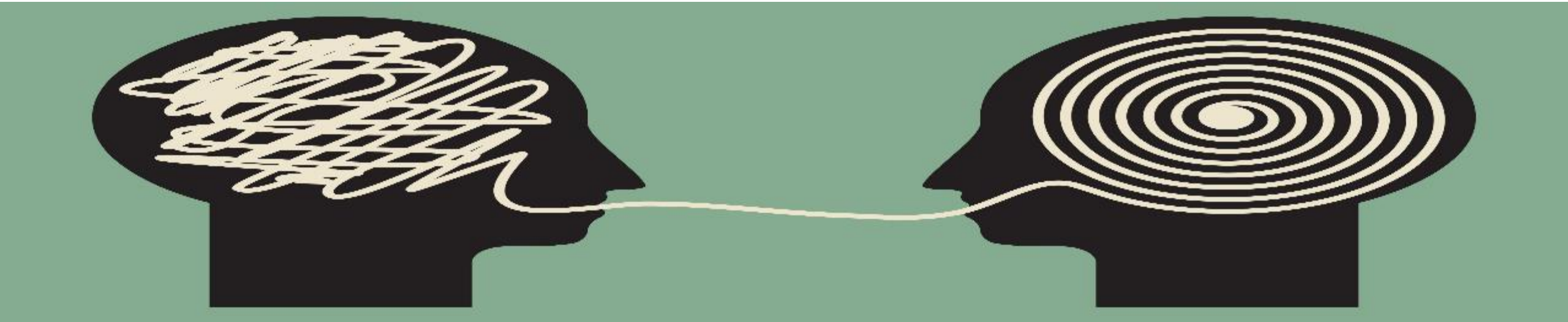
The allogeneic donor shall be informed of the **potential consequences** to the recipient of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.

Examples of written criteria for allogeneic donors

- Infectious disease markers obtained within the appropriate time frame before collection for a donor. (**EU regulations**)
- Criteria for an ineligible but acceptable donor (for example, an international donor may be ineligible but acceptable if all other donor criteria are fulfilled).
- Number of times a sibling donor can donate cells

Translation / Interpretation

- Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.
- Family members and legally authorised representatives should **not** serve as interpreters or translators.



Consent process

1. Consent from the allogeneic donor should be obtained by a licensed health care professional **other than the intended recipient's primary health care professional**

2. Donor shall give informed consent and authorization in advance to release the donor's health information to the transplant physician and/or the recipient as appropriate

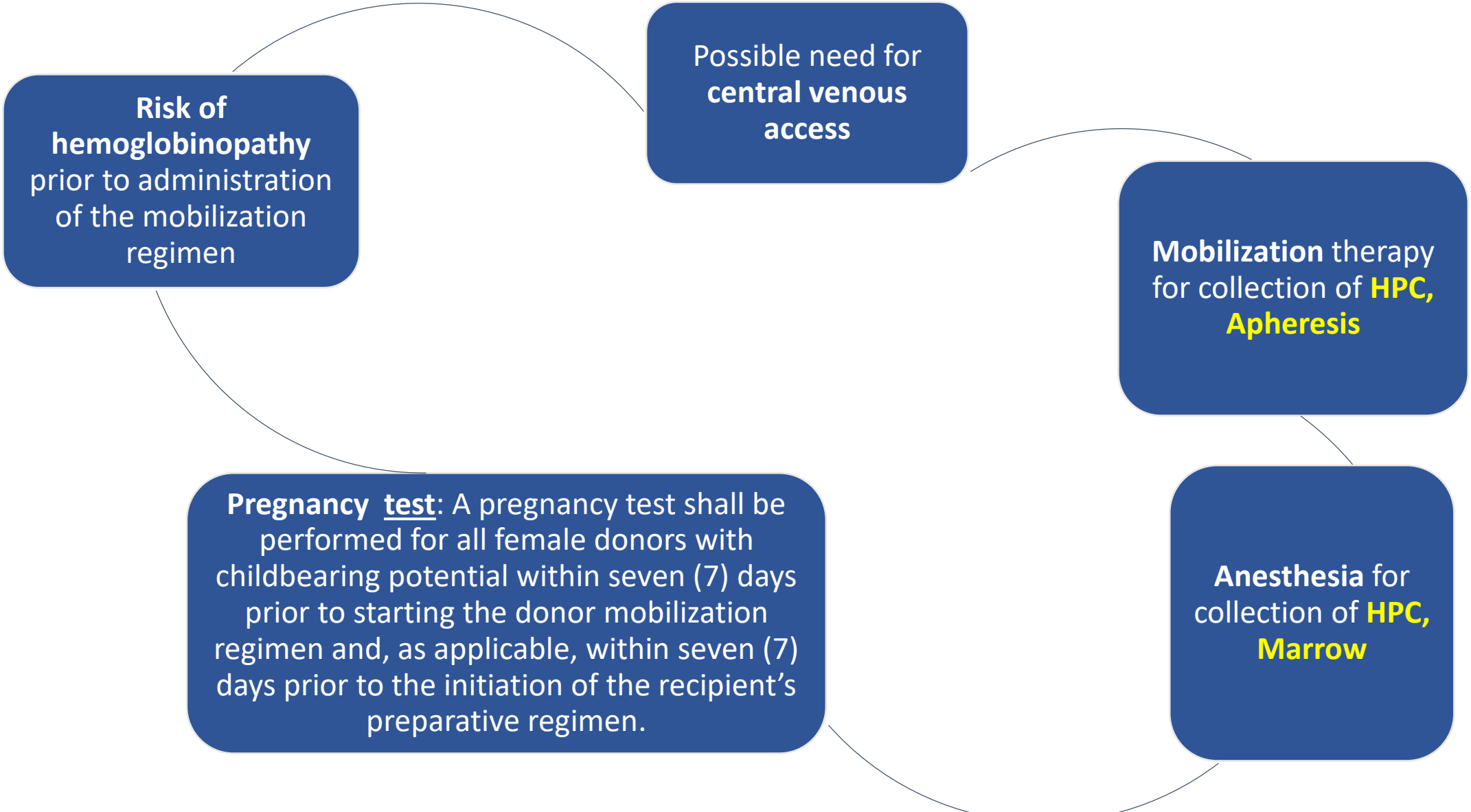
3. Documentation of consent shall be available to the Collection Facility staff **prior to the collection procedure**

Storage & discard policy

The donor shall be informed of

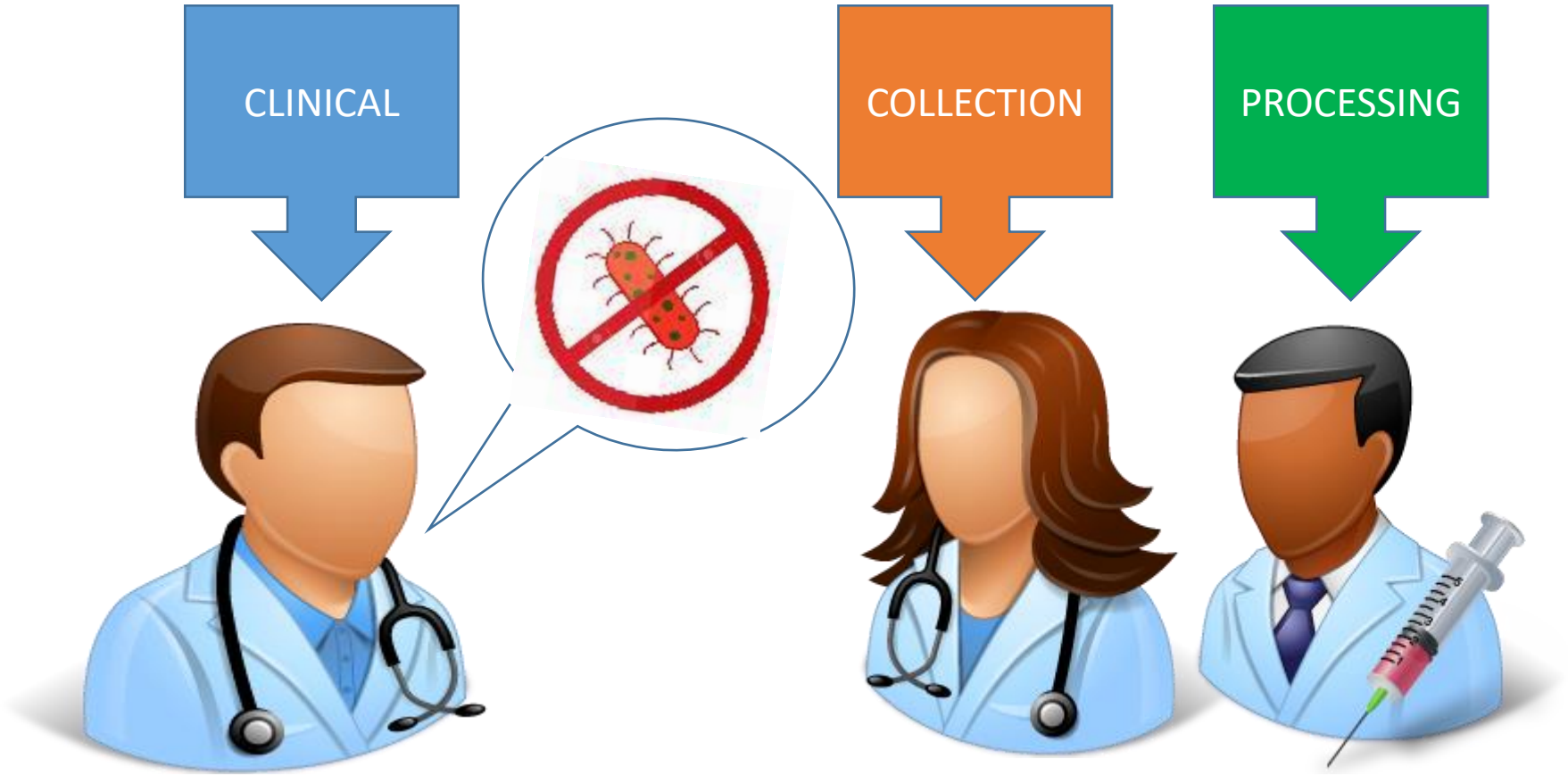
- the policy for cellular therapy product discard or disposal,
- including actions taken when an intended recipient no longer requires the cellular therapy product.

Allogeneic and Autologous Donor Suitability for CTP Collections



Test results communication

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



Donor assessment for hemoglobinopathy

- The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilisation regimen.

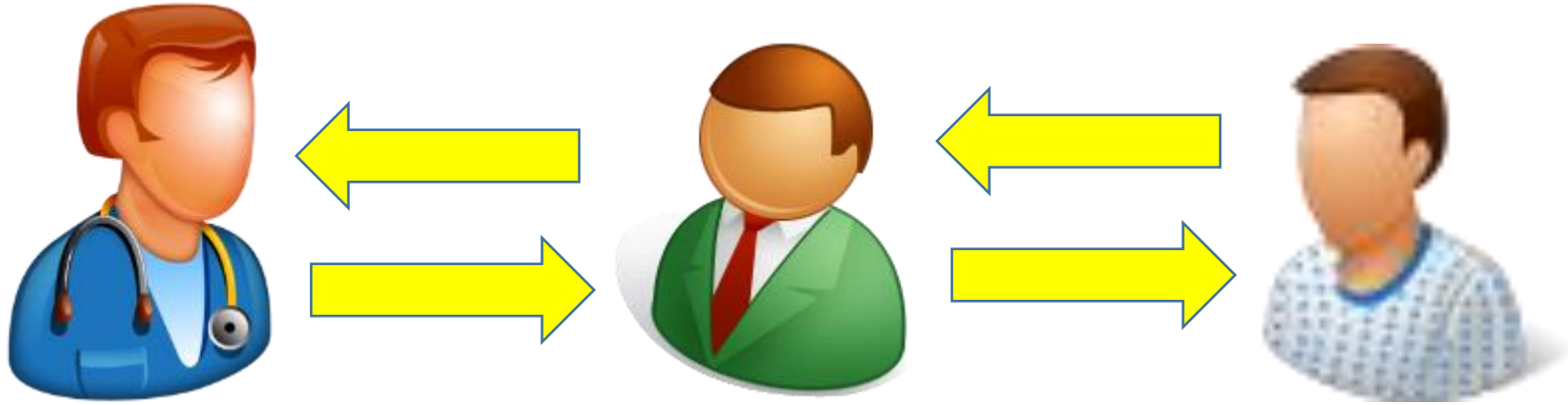
- Inspection Manual:
  - Hemoglobinopathy risk assessment may include testing for the detection of Hemoglobin S (e.g. Sickle Dex) or an Hb-electropheresis test, but a **test is not** required.

Donor follow-up

There shall be policies or Standard Operating Procedures for:

- follow-up of donors that includes routine management and
- the management of collection-associated adverse events.

Donor advocate



FOR WHOM?

To represent allogeneic donors who are:

- Minors

or

- Mentally incapacitated
- As defined by applicable laws

Donor advocate

- NOT the donor's primary physician
- Objective to safeguard that the consent is made without pressure
- To facilitate the process

- *Bone Marrow Transplantation* (2010) **45,** 1269–1273; doi:10.1038/bmt.2009.354; published online 21 December 2009:Family donor care management: principles and recommendations

Additional requirements for allogeneic donors

Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type **using two independently collected samples**

A red cell antibody screen shall be performed on allogeneic recipients

Allogeneic donors' clinical history

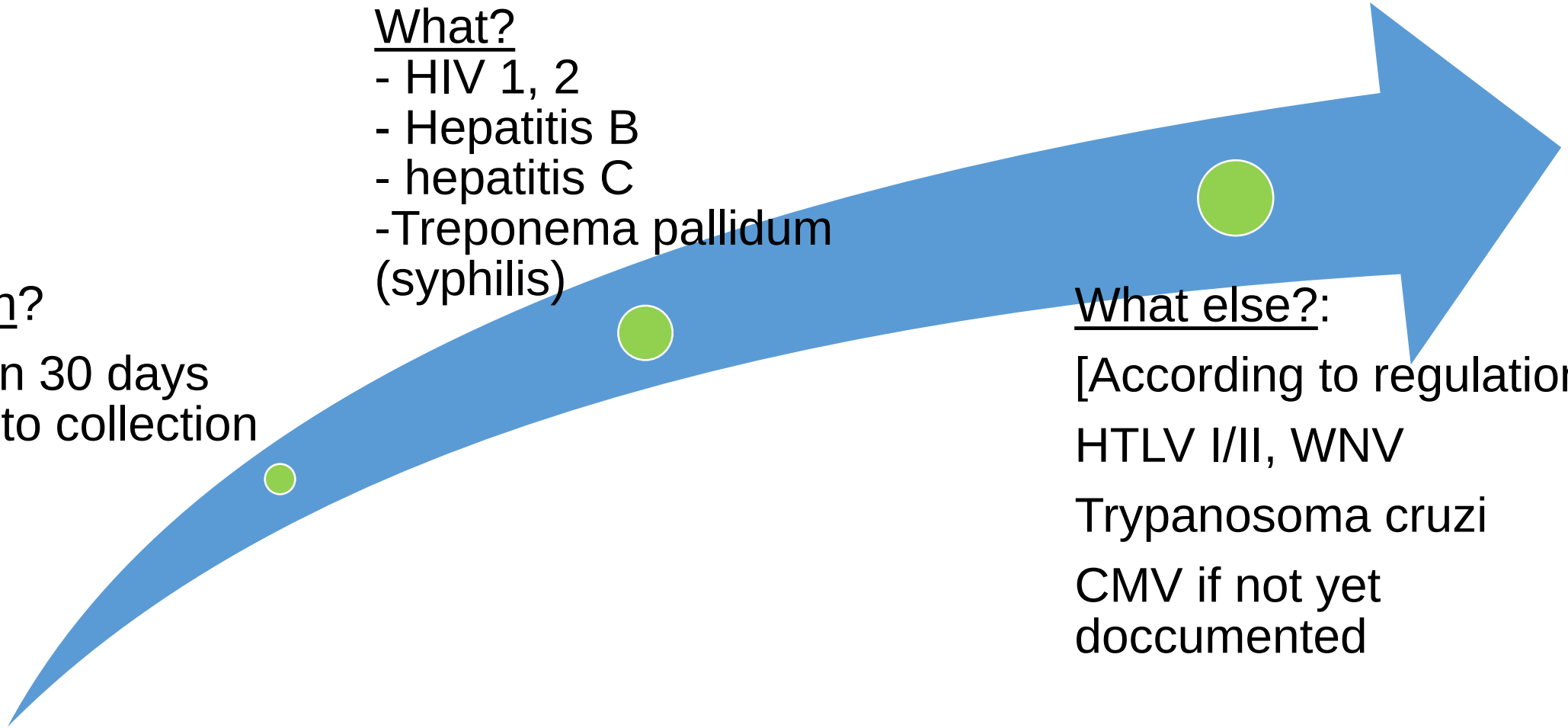
- Vaccination history
- Travel history
- Blood transfusion history
- Communicable disease
- Inherited conditions
- Hematological or immunological disease
- Malignant disease

Allogeneic donors' clinical history

- **Evidence:**
- Donor medical examination notes and questionnaire records can be reviewed to determine if all of the required screening elements were included in the eligibility determination.
- **Example(s):**
- It is recommended that the Clinical Program utilize a screening tool used by an unrelated donor registry even for related donors, such as the National Marrow Donor Program's "Donor Health History Screening Questionnaire." Information about areas of the world where CJD is a risk factor can be obtained from the interorganizational Uniform Donor History Questionnaire developed for donors of HCT/Ps and the algorithm that accompanies it. This information is available on the FACT website (www.factwebsite.org).

- Note: Standards point to specific questionnaire – not general medical history assesment.

Allogeneic donors – testing for communicable disease agents



When?

Within 30 days prior to collection

What?

- HIV 1, 2
- Hepatitis B
- hepatitis C
-Treponema pallidum (syphilis)

What else?:

[According to regulations]

HTLV I/II, WNV

Trypanosoma cruzi

CMV if not yet doccumented

HLA typing

B6.4.12 Allogeneic donors and recipients shall be tested at a minimum for **HLA-A, B, DRB1** type by a laboratory accredited by **ASHI, EFI**, or equivalent. **HLA-C** testing shall be performed for **unrelated allogeneic donors** and related allogeneic donors other than siblings.

B6.4.12.1 DNA **high resolution molecular typing** shall be used for DRB1 typing.

B6.4.12.2 **Verification typing/CT** shall be performed using an **independently sample** prior to allogeneic donor selection.

Donor Eligibility & Clearance

Determined by a physician after review of:

- History
- Medical exam
- Medical record review
- Testing / results

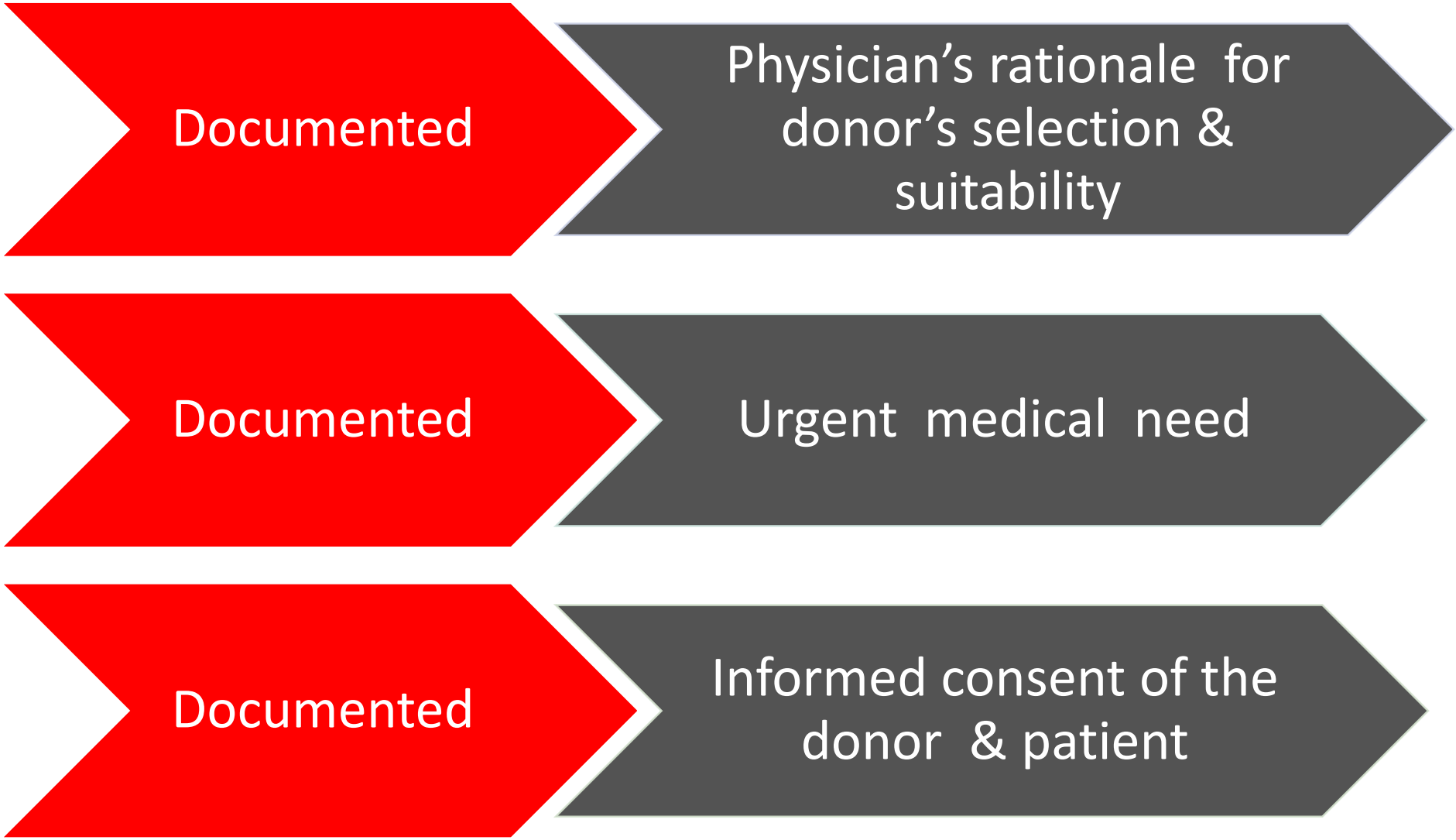
Documented in the recipient's medical record <u>before</u>:

- Recipient's preparative regimen is initiated
- Allogeneic donor begins mobilization regimen

Use of an ineligible allogeneic donor – Requirements:

- Rationale for use of that donor
- Documented Informed Consent - donor and recipient
- Documentation in the medical record of urgent medical need
- Product accompanied by a summary of records to the Collection and Processing Facilities stating reasons the donor is ineligible
  - including results of health history screening, physical examination, and results of infectious disease testing.

Use of an ineligible allogeneic donor



Donor Records

- B6.4.17 There shall be a policy covering the creation and retention of allogeneic donor records

Regulations

- The Apheresis Collection Facility shall abide by all applicable laws and regulations
  - … licenced, registered, or accredited as required by the appropriate governmental authorities for the activities performed

Collection Facilities

ttp://jamailsmith.com/wp-content/uploads/2013/07/parklandcasestudy.jpg

http://www.medicaltourismmag.com/wp-content/uploads/2008/06/bone-marrow-transplantation-in-downtown-makati-main.jpg

Physical space

Appropriate designated areas for

- collection of cellular therapy products
- for collected products,
- for storage of supplies, reagents, and equipment.

Divided into defined areas of adequate size to prevent

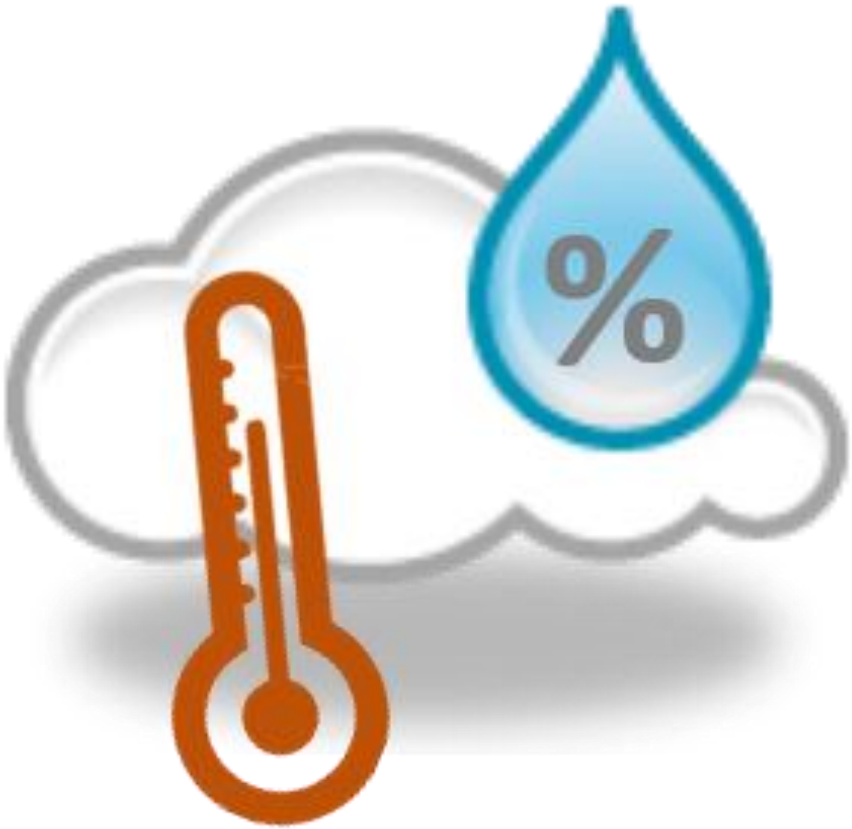
- improper labeling
- mix-ups
- Contamination
- cross-contamination of cellular therapy products.

Designated area with

- appropriate location
- adequate space
- design to minimize the risk of airborne microbial contamination in outpatient units where collection is performed.
- suitable space for confidential donor examination and evaluation

Physical space

- Controlled environment



Safety

- The Collection Facility shall have a written safety manual that includes instruction for action in case of exposure to communicable disease and to chemical, biological or radiological hazards
  - Hospital health & safety manuals; Hospital-wide procedures

Personnel

- **Apheresis Collection Facility shall have an**
  - **Apheresis Collection Facility Director**
  - **Medical Director**
  - **a Quality Manager**
  - **at least one additional designated staff member**

- **Marrow Collection Facility shall have :**
  - **Medical Director**
  - **a Quality Manager**
  - **at least one additional designated staff member**

http://news.christianacare.org/wp-content/uploads/2014/01/LDL-Apheresis-800x500.jpg

Experience

- A minimum of **ten cellular therapy products** shall have been collected by apheresis in the twelve month period immediately preceding facility accreditation, and a minimum average of 10 cellular therapy products shall have been collected by apheresis per year within the accreditation cycle.
- A minimum of **1 marrow collection procedure** shall have been performed in the twelve month period immediately preceding facility accreditation, and a minimum average of 1 procedure per year within the accreditation cycle.

BACKUP COVERAGE OF STAFF

Identified trained backup to maintain sufficient coverage.

Minimum of one designated trained individual

http://www.nhsbt.nhs.uk/images/content/specialist_services.jpg

Personnel

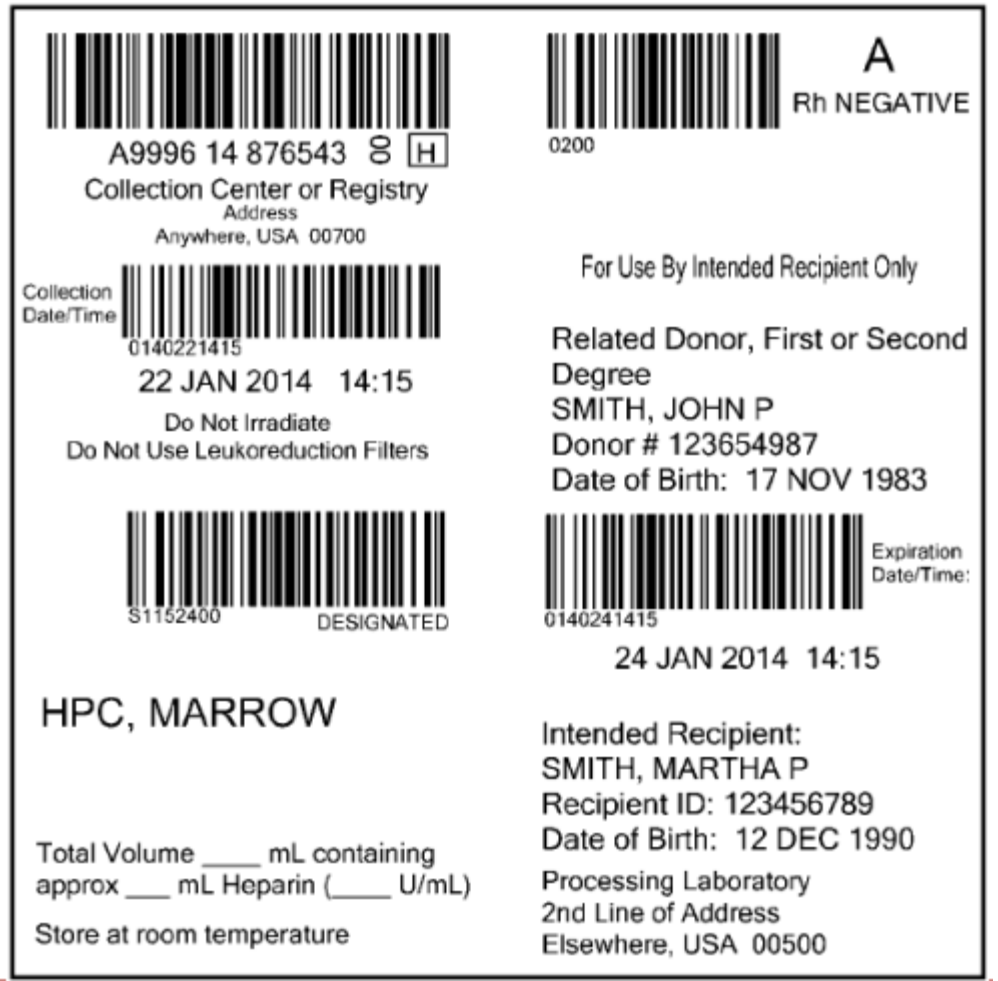
- Required staffing specified

- All staff must
  - have relevant qualifications
  - have specified training and competent in the procedures they undertake
  - have plan for continuing education

LABELLING - ISBT 128 & EUROCODE

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

https://www.iccbba.org/



EUROCODE-IBLS

http://www.eurocode.org/index.html

LABEL CONTENT

At all stages of collection, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.

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

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 II

Process Controls

- Equipment shall be inspected for cleanliness and verified to be in compliance with the maintenance schedule 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.

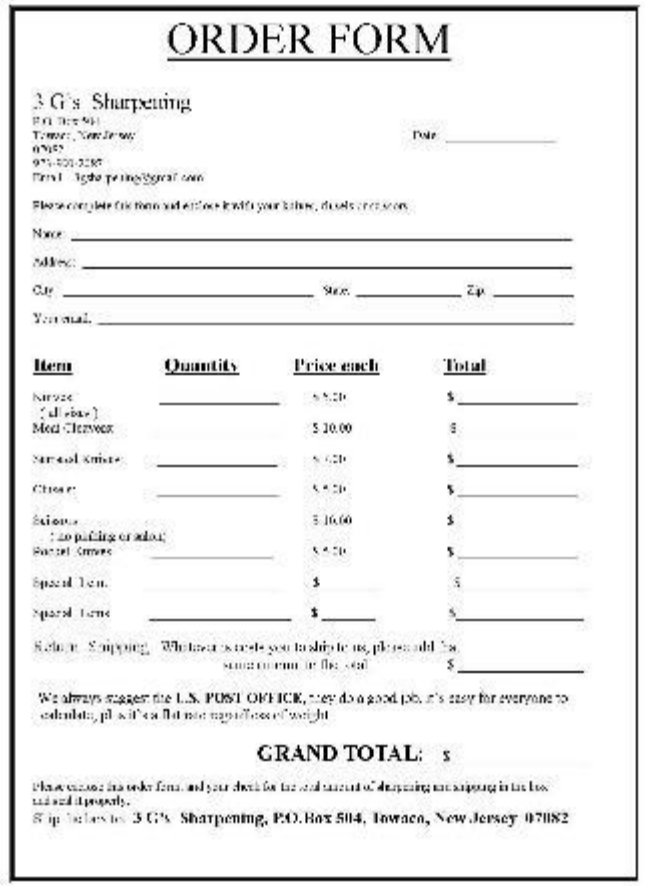
Process Controls

- 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.

Process Controls

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

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



ORDER FORM

3 G's Sharpening

Date: _____

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Your email: _____

Item	Quantity	Price each	Total
Knives (all sizes)	_____	$ 5.00	$ _____
Meat Cleaver		$ 10.00	$
Serrated Knives	_____	$ 6.00	$ _____
Cleaver	_____	$ 5.00	$ _____
Scissors (no pinking or other)		$ 16.00	$
Pocket Knives	_____	$ 5.00	$ _____
Special Item		$	$
Special Items	_____	$ _____	$ _____

Select Shipping. Whatever route you decide to ship to us, please add the same amount to the total $ _____

We always suggest the U.S. POST OFFICE, they do a good job, it's easy for everyone to calculate, plus it's a flat rate regardless of weight

GRAND TOTAL: $

Please enclose this order form and your check for the total amount of sharpening and shipping in the box and seal it properly.

Ship to/Address to: 3 G's Sharpening, P.O. Box 504, Towaco, New Jersey 07082

Process Controls

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

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

Process Controls

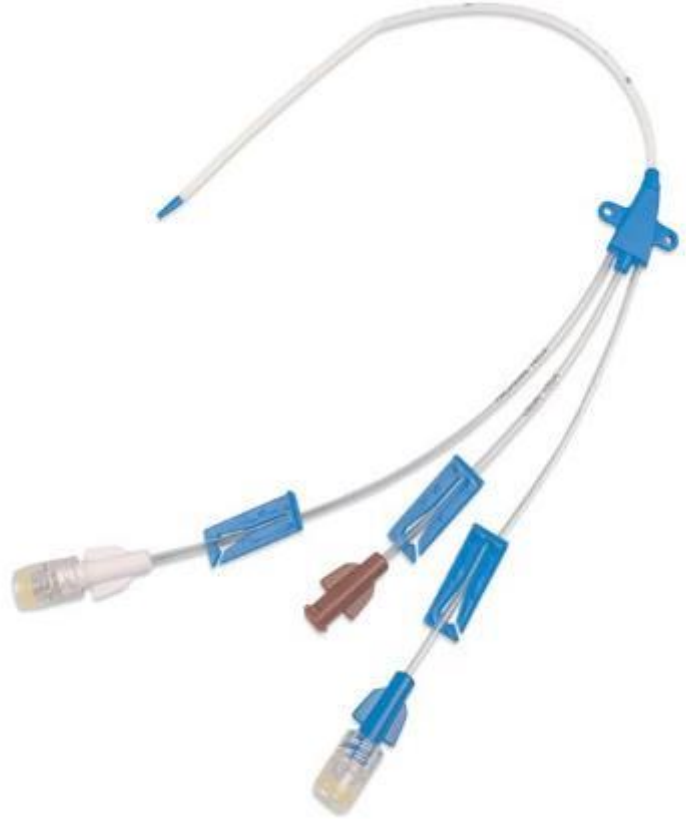
There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.

Explanation:

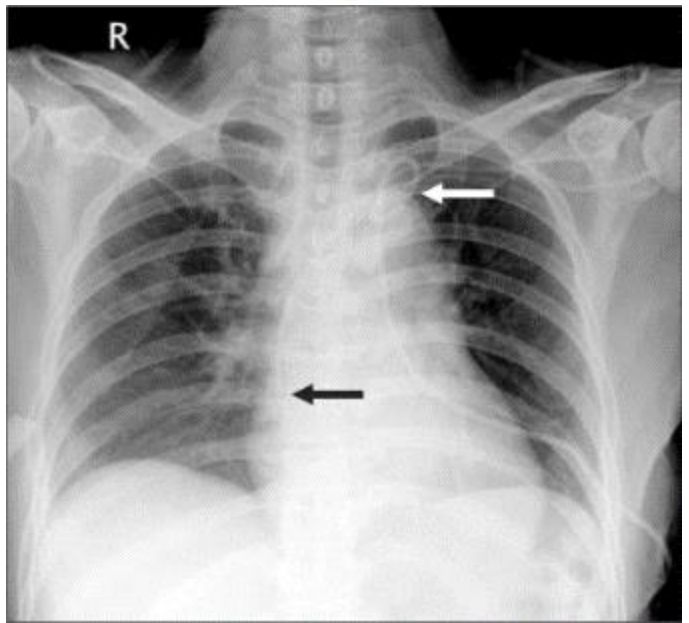
Day-to-day management of the donor is the responsibility of the Apheresis Collection Facility. It is incumbent on the collection team to confirm the health of the donor at the time of collection. This does not require a complete history and physical examination by a physician for each collection procedure. Rather, the records from the initial evaluation (including consent for the procedure and documents regarding the goals of the collection procedure) must be immediately available to and reviewed by the collection team. A physician or registered nurse on the collection team must evaluate the donor before each collection procedure to determine if there have been changes in the health of the donor or changes in medications since the last donation.

Process Controls

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



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



Process Controls

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

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

Process Controls

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.

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

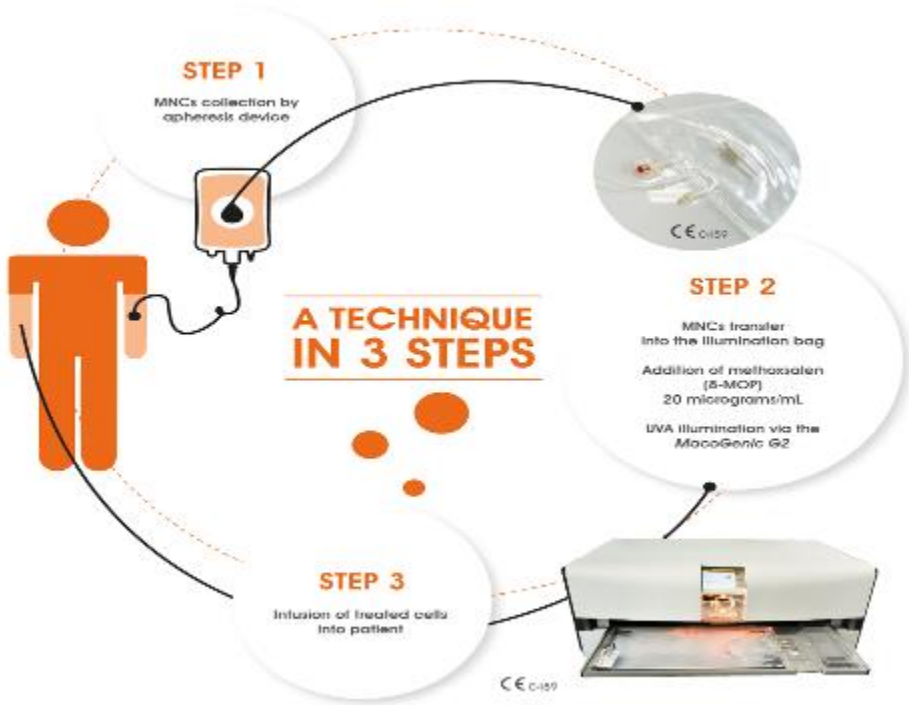
Explanation: Records must be used during cellular therapy product collection and must be completed in real time as the procedure is performed. Records must be accurate, indelible, and legible, and must identify the person performing the work and the dates of the various entries. Records of identification codes of personnel including methods to link the name and/or signature to the initials or other identification codes used in other documents and records must be maintained. These records should include dates of employment of the personnel

Extracorporeal Photopheresis (ECP)

There shall be a policy addressing safe administration of ECP

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.

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



Transportation & Shipping

Shipping:

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

Transport:

- Physical act of transferring within or between facilities.
- Product **does not leave the control** of trained personnel at the transporting or receiving facility.

Transportation & Shipping

Products are packaged in a closed sterile transfer pack appropriate for blood products

Policies for duration and conditions of **short-term storage** prior to distribution

Primary cellular therapy product container shall be placed in a secondary container that is sealed

Transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a SOP

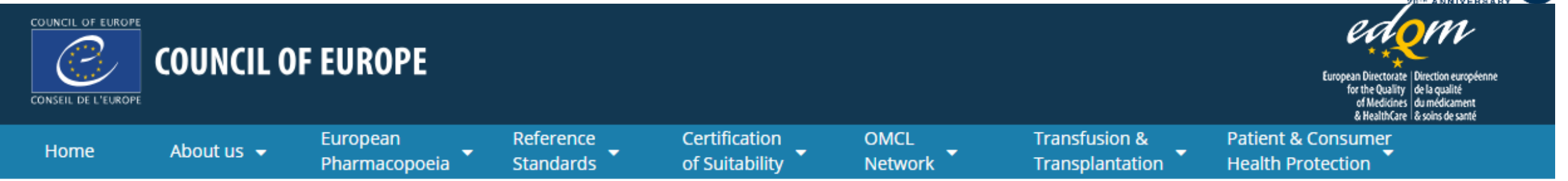
Records

- Records management often part of the hospital system – but can be stand alone
- Confidentiality of records
- Retain for minimum of 10 years or longer in accordance with applicable laws and regulations (program or institutional policy
- Electronic records
  - Listing of all critical electronic systems = systems that are under the control of the Apheresis Collection Facility that are used as a substitute for paper, to make decisions, to perform calculations…
  - Must have policies, SOPs to maintain accuracy and confidentiality
  - Alternative system to allow for continuous operation if the electronic record s are not available – must be validated.
  - Validated procedures for and documentation of training and competencies; monitoring of data integrity; back up & system for assigning unique identifiers.

Electronic records

Critical electronic record systems shall include at a minimum systems

- under the control of the Collection Facility
- that are used as a substitute
  - for paper
  - to make decisions
  - to perform calculations
  - or to create or store information used in critical procedures.



Revised: "Validation of Computerised Systems" Guideline

Back

AGENDA

- https://www.edqm.eu/en/news/revised-validation-computerised-systems-guideline

The revised guidelines are the following

- Validation of Computerised Systems - Core Document
- Validation of Computerised Systems Annex 1: Validation of Excel Spreadsheets
- Validation of Computerised Systems Annex 2: Validation of Complex Computerised Systems

Direct distribution to clinical program

- Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program for administration of for subsequent processing, the Standards related to labelling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13 and the Appendices apply.