DONOR CARE & MANAGEMENT

6th edition of FACT-JACIE Standards

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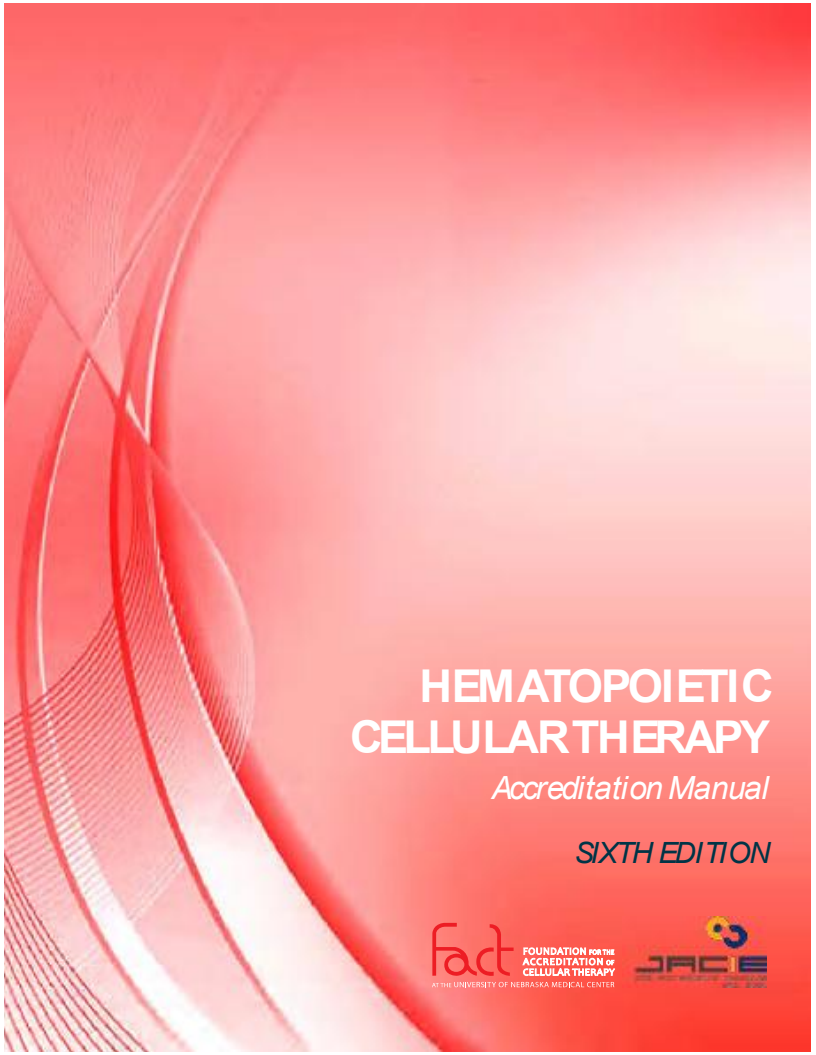
6th edition



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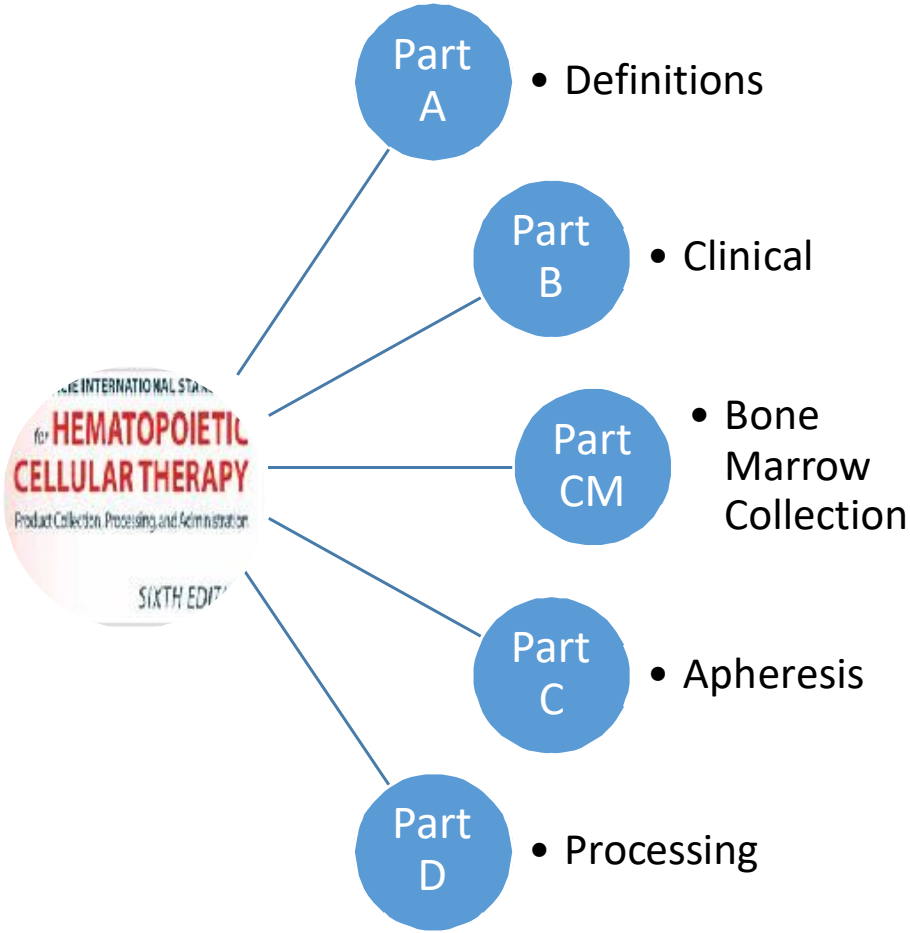
JACIE joint accreditation committee
EBMT European Society for Blood and Marrow Transplantation
International Society for Cellular Therapy ISCT

FACT-JACIE Standards



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	

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.

CM/C 6 and B 6:

Standards in C6 mirror those in B6, reflecting the fact that these responsibilities are usually the primary responsibility of the Clinical Program staff. Apheresis Collection Facility staff are usually not responsible for donor selection. Cellular therapy program policies and SOPs must clearly define responsibility for all aspects of donor selection, evaluation, eligibility (allogeneic donors only) and suitability determination, and management. In situations in which the Apheresis Collection Facility is primarily responsible for activities related to donor selection, the applicant and inspector must complete the corresponding sections in the Clinical Program inspection checklist.

Communication

- Communication between all involved parties is essential for the success of the program
- Lies at the very heart of FACT-JACIE philosophy
- Distinguishes FACT-JACIE from most regulatory / accreditation / certification requirements
- Look for evidence of active and regular communication

Definition

- Donor: A person who is the source of cells or tissue for a cellular therapy product.

- The term “donor” is used by these 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.

Standards B/CM/C 6:

- 6.1 THERE SHALL BE WRITTEN CRITERIA FOR ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT BY TRAINED MEDICAL PERSONNEL.
- 6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE
- 6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION
- 6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

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

- These 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 B/CM/C 6 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 sub-standards under B/CM/C6.1, 6.2, and 6.3 apply to autologous transplantation except for those that specify allogeneic donors only.

Required Standards for Autologous-only Clinical Programs

Subject	Substandards	
B6.1 Written criteria		
B6.2 Informed Consent	B6.2.1	B6.2.1.1
		B6.2.1.2
		B6.2.1.3
		B6.2.1.4
		B6.2.1.5
	B6.2.2	
	B6.2.3	
	B6.2.4	
	B6.2.5	
	B6.2.6	
	B6.2.7	
	B6.2.9	
	B6.2.10	
B6.3 Donor Suitability	B6.3.1	B6.3.1.1 B6.3.1.3
	B6.3.2	B6.3.2.1
		B6.3.2.2
		B6.3.2.3
	B6.3.3	
	B6.3.4	
	B6.3.5	
	B6.3.6	
	B6.3.7	
	B6.3.8	
	B6.3.9	
	B6.3.10	

B/CM/C 6.1

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

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

Written criteria for allogeneic donor selection, evaluation, and management

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.

Examples of written criteria for allogeneic donors include:

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

Allogeneic and autologous donor evaluation and management

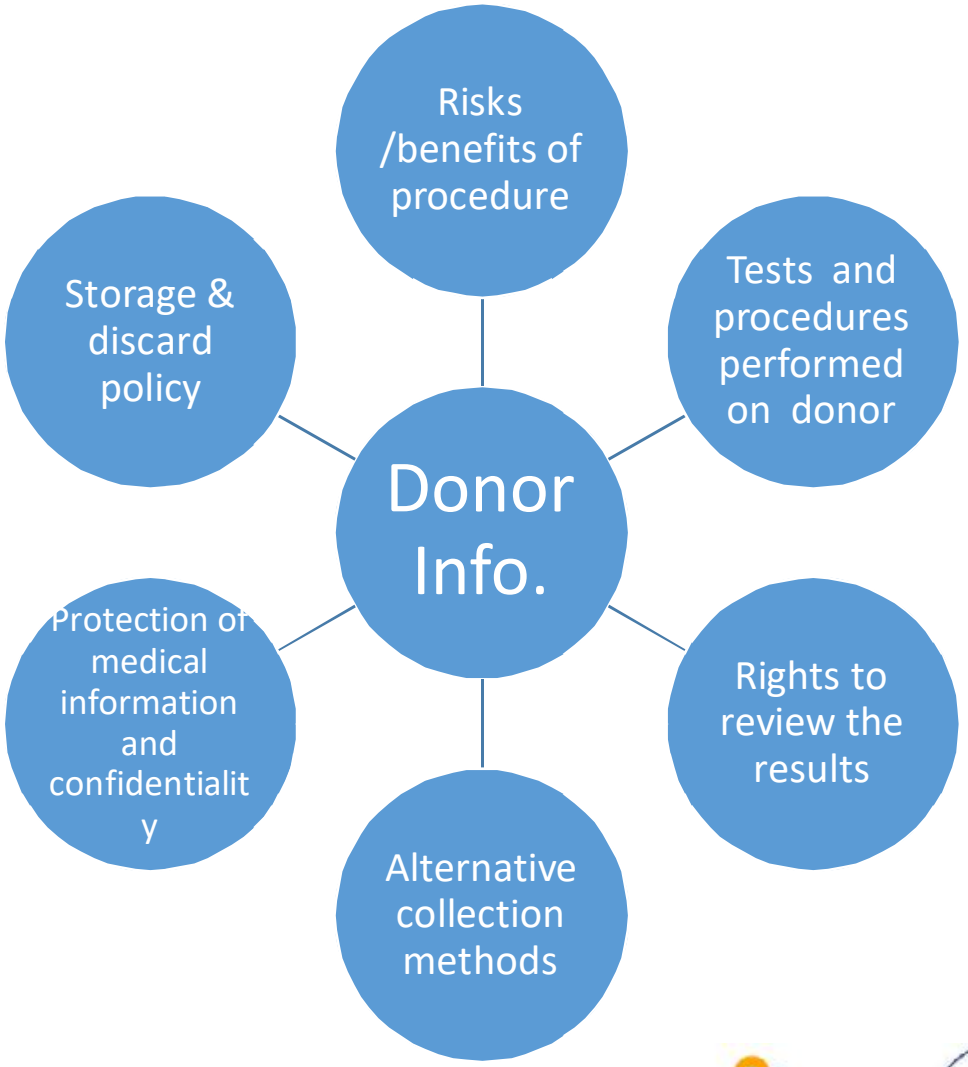
- **B/CM/C 6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION**

- **B/CM/C 6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION**

B/CM/C6.2 Donor rights

- Opportunity to ask questions and receive full information
- Right to refuse to donate
  - B/CM/C 6.2.5.1 Allogeneic donor shall be informed of the potential consequences to recipient of such refusal

B6.2.1 Minimum donor information



B6.2.2/3 Translation / Interpretation

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

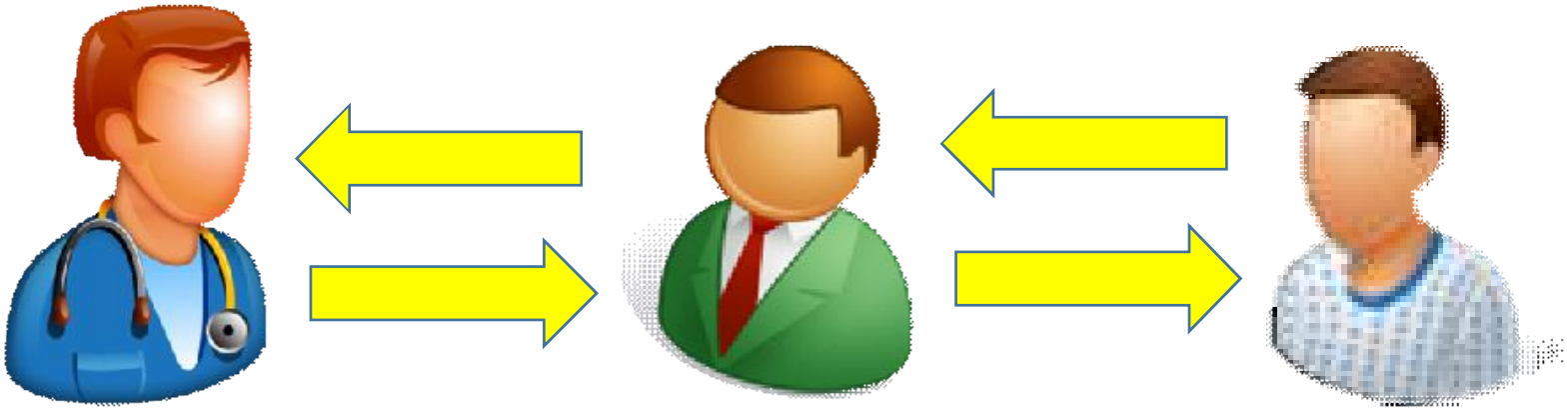
B6.2 Consent process

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

B/CM/C6.4.1 Donor advocate



FOR WHOM?

To represent allogeneic donors who are:

- Minors

or

- Mentally incapacitated
- As defined by applicable laws

6th edition – now obligatory (“shall”)

B6.2.9 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.

B6.3.2 Risk evaluation

- Possible need for **central venous access**
- **Mobilization** therapy for collection of HPC, Apheresis
- **Anesthesia** for collection of HPC, Marrow
- **Pregnancy test**: within 7 days before mobilization/collection or initiating patient's preparative regimen (whichever occurs earliest)
- **Risk of hemoglobinopathy** prior to administration of the mobilization regimen

Risk of hemoglobinopathy

- B6.3.3 / C6.3.3
  - The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization 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.

B6.4 Additional requirements for allogeneic donors

B6.4.3 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples

B6.4.4. A red cell antibody screen shall be performed on allogeneic recipients

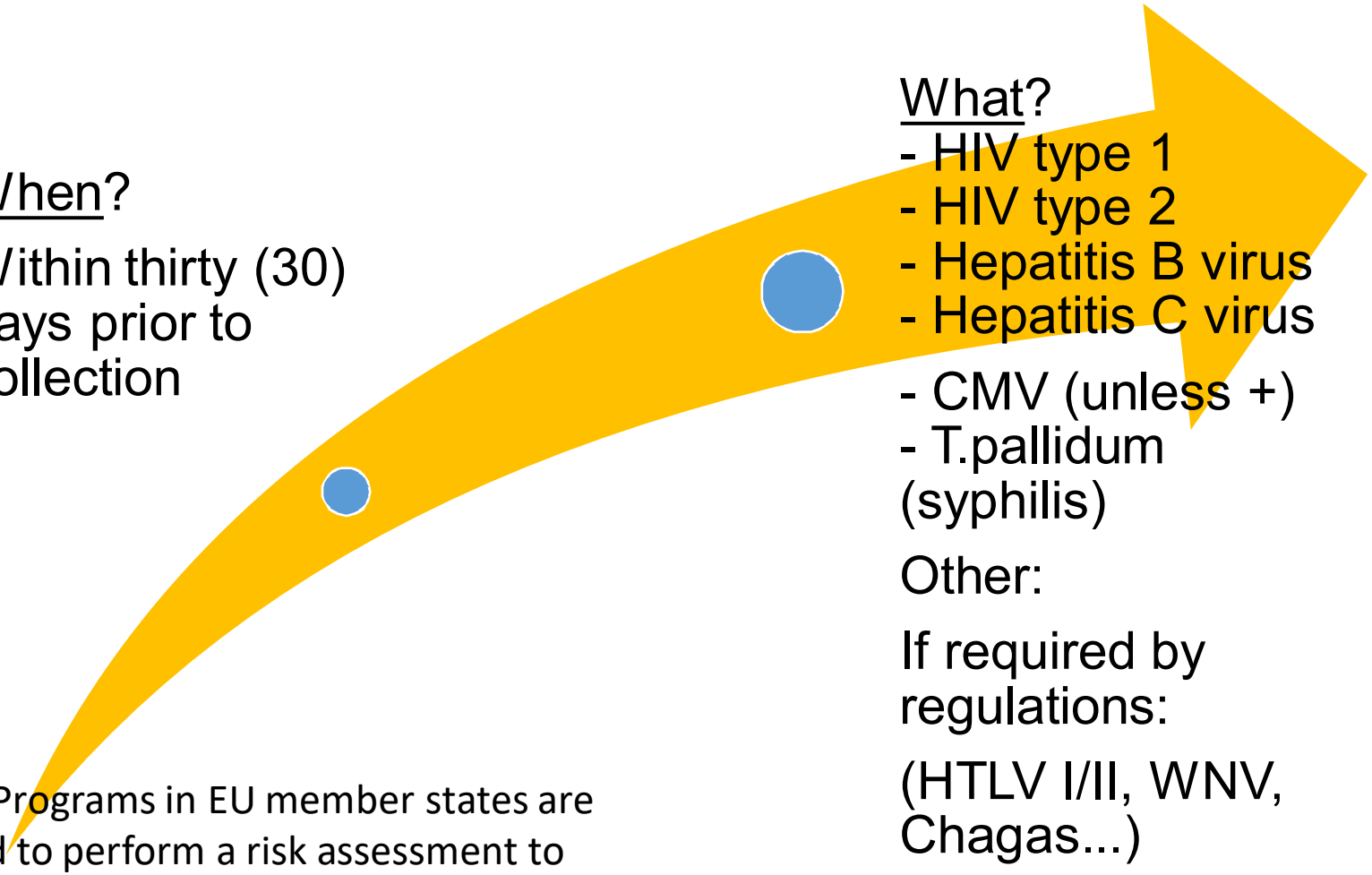
HLA typing

- 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.
- DNA **high resolution molecular typing** shall be used for DRB1 typing.
- **Verification typing** shall be performed using an **independently sample** prior to allogeneic donor selection.

B6.4.6 Medical History & Risk Evaluation for Allogeneic Donors

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

B6.4.5 Disease testing



When?

Within thirty (30) days prior to collection

What?

- HIV type 1
- HIV type 2
- Hepatitis B virus
- Hepatitis C virus
- CMV (unless +)
- T.pallidum (syphilis)

Other:

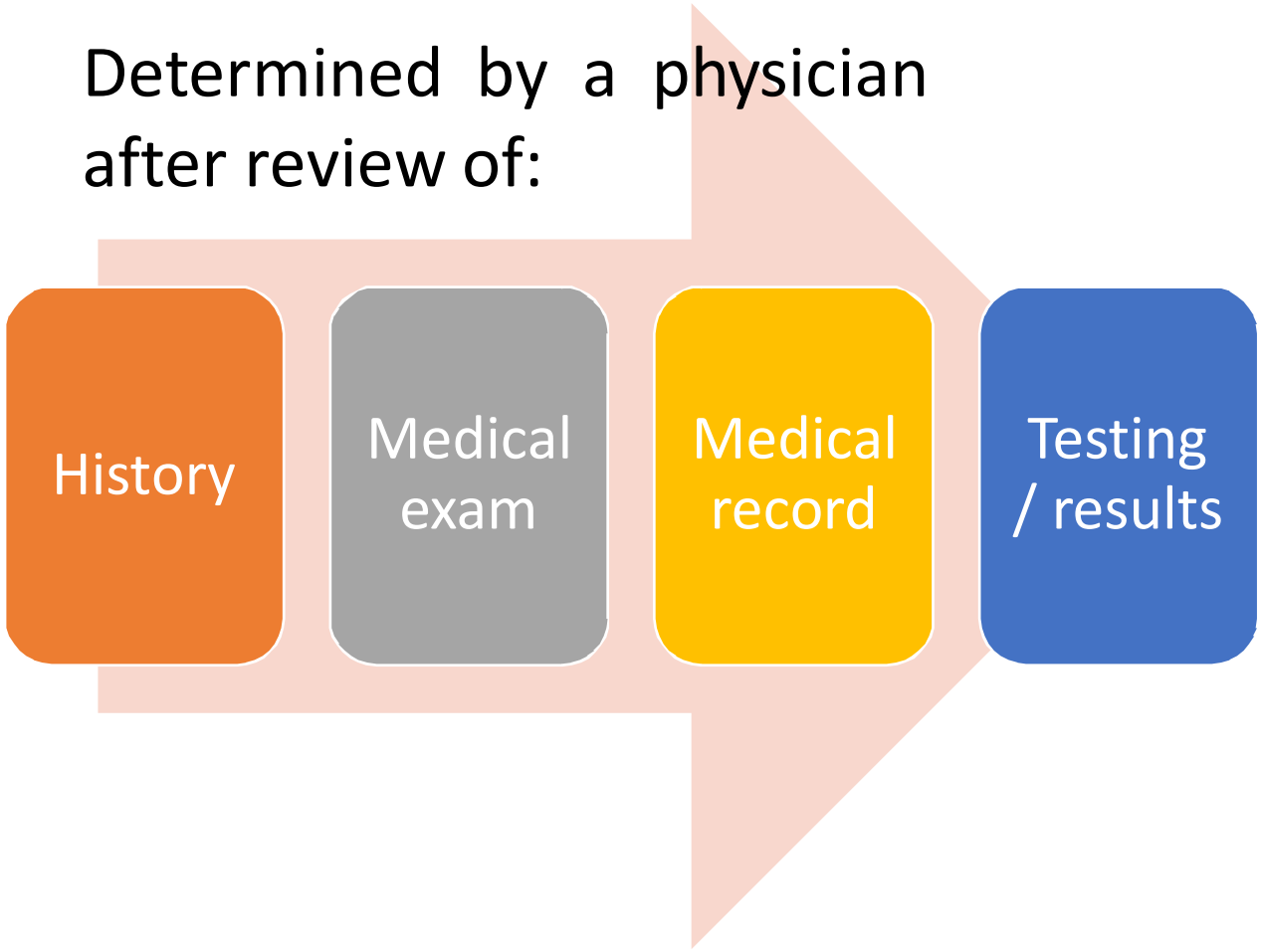
If required by regulations:

(HTLV I/II, WNV, Chagas...)

Clinical Programs in EU member states are required to perform a risk assessment to determine if testing for HTLV I and II or other diseases is appropriate for their patient populations.

B6.4.13 Donor eligibility

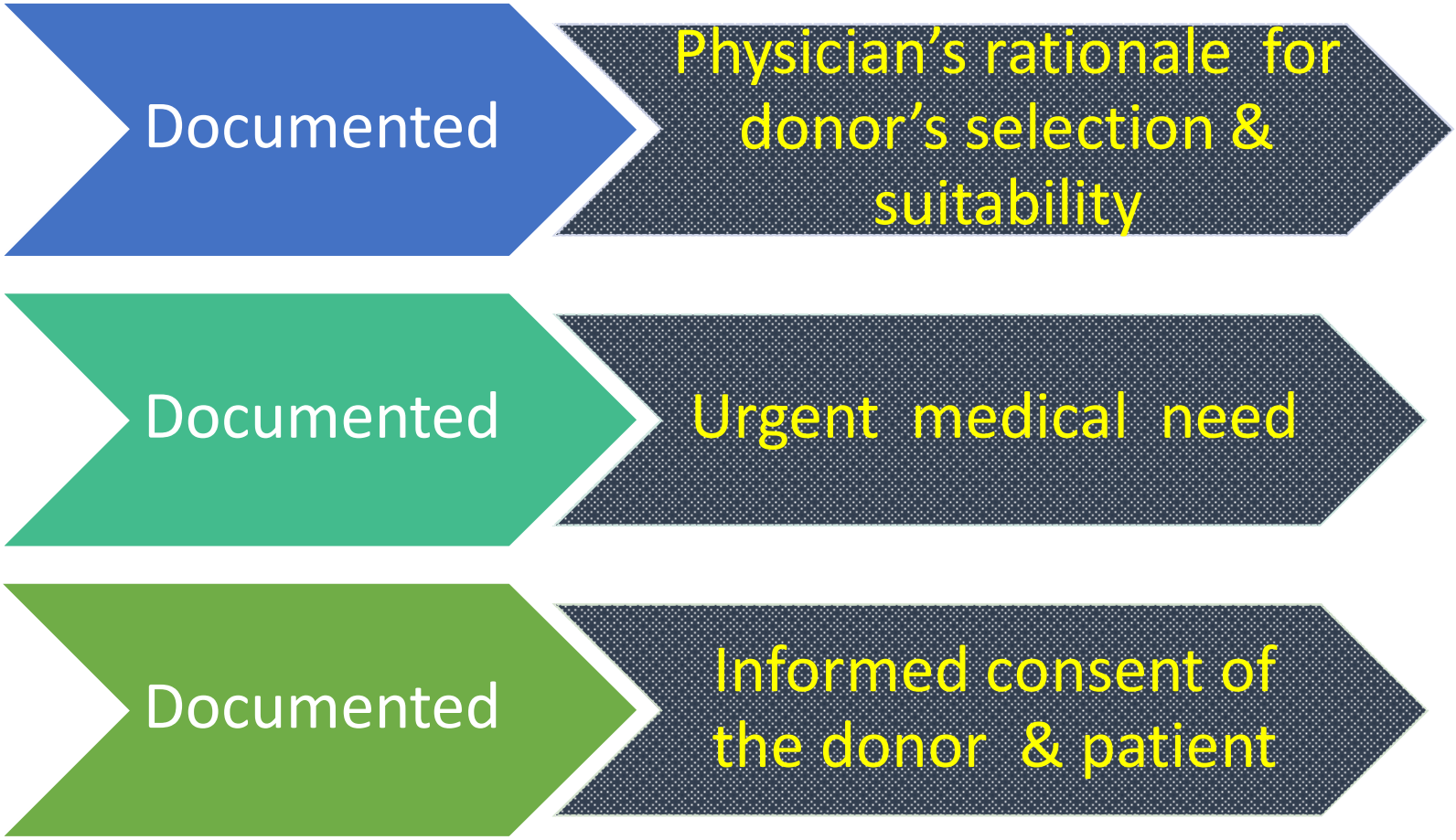
Determined by a physician after review of:



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

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

B6.4.13 Use of an ineligible allogeneic donor



C6.3.6 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 follow-up

C6.3.9 There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.

Summary of Changes B/CM/C 6
Donor selection, Evaluation and Management

10. Donor Selection, Evaluation, and Management (B6, CM6, C6)
    a. The Clinical Program must have written criteria for selection of allogeneic donors who are elderly in addition to those who are minors.
    b. Interpretation and translation must be performed by individuals qualified to provide these services in the clinical setting.
        i. The Standards recommend that family members and legally authorized representatives not serve as interpreters or translators. It is expected that every effort be made to avoid this situation, but it is also understood that many centers treat patients who speak uncommon languages.
    c. Informed consent and donor evaluation now must be obtained by a health care professional who is not the primary health care professional overseeing care of the recipient. This was only a recommendation in the 5th edition.
    d. The informed consent process must inform the donor of the policy for cellular therapy product discard or disposal.

e. Pregnancy tests are now required.
    i. Previous editions only required a pregnancy assessment for female donors with childbearing potential, which was often misinterpreted.
    ii. Tests must be performed within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen. This is particularly important when the recipient is on a long-term (for example, 21-day) preparative regimen.
f. The requirement for a written order from a physician specifying the timing and goals of collection and processing is now also included in the clinical standards.
g. The requirement for verification typing of the selected donor, with results confirmed prior to administration of the preparative regimen, is more explicitly stated in response to many questions.
h. Clinical Programs must have a policy for anti-HLA antibody testing for mismatched donors and recipients.
i. Records required for donor eligibility determination must be in English or translated into English when crossing international borders.
j. Standards throughout the document explicitly reference requirements for incomplete donor eligibility determination in addition to ineligible donors.

Thank you for your attention!