Standard operating procedure (SOP) · FRT-SOP-007 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 8.11

At a glance

- Every tissue or organ has a documented chain of custody from donor to recipient.
- Each handling, test and transport step is signed.
- There is no gap in the record at any point.
- A gap stops use until it is resolved.
- Stop and get help straight away if: a tissue or organ is used or moved with a gap in its chain of custody.

1. Purpose

To trace every tissue or organ from donor to recipient with no gap (8.11).

2. Scope

Applies to	Clinical and support staff in the hospital
Locations	All wards, clinics and departments of the facility
When	Whenever the activity described is carried out
Does not apply to	Activities covered by another document listed in section 15

3. Definitions

Term	Meaning
Clinical lead	The doctor or nurse in charge of the area at the time

4. Background

An organ or tissue must be traceable from donor to recipient, through every step of handling, testing and transport. Without a chain of custody, an unsafe donation cannot be found or stopped.

5. Responsibilities

Role	Responsibility	Competence
Clinical director	Owns the chain of custody	Clinician
Coordinator	Keeps the record at each step	Coordinator

6. Materials and equipment

Item	Requirement	Condition
Records and forms named in this document	Current version	Checked before use

7. Safety

- Stop and call for help if a patient is at immediate risk. Do not delay urgent care to complete paperwork.

8. Before you start

- Confirm the forms and equipment named in this document are available and current.

9. Procedure

Step 1. Start the chain.

- Record the donor and the tissue or organ identity at collection (FRT-FRM-005).

Key point: The chain starts at donation.

Step 2. Sign each step.

- Sign each handling, test and transport step with the time and the condition.

Key point: No step without a signature.

Step 3. Close.

- Close the chain at the recipient, and check there is no gap.

Key point: No gap at the end.

10. Decision points

- No decision points in this procedure.

11. Special situations

Situation	Action
Out of hours	Follow the same steps. Use the on-call contact on the wall of the area.

12. Escalation

- Any serious problem goes to the duty clinical lead at once and to the clinical director the same day.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Chains with no gap	100%	Quarterly	Clinical director	Escalate to chief executive

14. Records

Record	Kept in	Retention
Record named in this document	Patient record or the area file	the period set by the facility’s records policy years

15. Training

- Staff are trained in this document at induction and refreshed each year, with a recorded competency check.

16. Related documents

ID	Title	Use
FRT-FRM-005	Chain of custody record	Record

17. Evidence

Reference	Note
E-009	Based on the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (2010).
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	set Expert Committee approval

E-learning for this document

- **Supplier Evaluation and Purchasing** (T-13)
- **Equipment, Reagents & Traceability** (LAB-04)

References

- Accréditation Sans Frontières (2026). ASF Policy Framework v1.2. (E-006)
- Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)

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