Standard operating procedure (SOP) · FRT-SOP-006 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 8.9

At a glance

- A suspected mix-up is reported to the senior embryologist at once.
- The affected gametes or embryos are contained at once.
- The patients involved are told openly, with support.
- The case is reported where guidance requires and reviewed.
- Stop and get help straight away if: a suspected mix-up is not reported at once, or the patients involved are not told.

1. Purpose

To contain a mix-up at once, tell the patients honestly and learn from it (8.9).

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

A gamete or embryo mix-up is a serious harm to patients and families. A written plan for containment, disclosure and review, rehearsed, is what the clinic must have before it happens.

5. Responsibilities

Role	Responsibility	Competence
Clinical director	Leads the response and the disclosure	Clinician
Senior embryologist	Contains the material and runs the trace	Embryologist

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. Contain.

- Stop use of the affected material at once and secure it. Record the time.

Key point: Stop first.

Step 2. Trace.

- Trace the material through FRT-REG-001 and confirm the patients involved.

Key point: Trace to the patients.

Step 3. Disclose and review.

- Tell the patients involved, with support, and report where guidance requires. Review the cause in the incident system (INC-FRM-001).

Key point: Open disclosure, then learning.

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
Suspected mix-ups reported at once	100%	Quarterly	Clinical director	Escalate to chief executive
Affected patients told within the set time	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-REG-001	Gamete and embryo traceability register	Register
INC-FRM-001	Root Cause Analysis Record	Review

17. Evidence

Reference	Note
E-009	Based on ESHRE revised guidelines for good practice in IVF laboratories (2015).
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

- **Incident Reporting, Just Culture and Open Disclosure** (T-09)
- **Fertility & IVF Accreditation Training** (AMB-13)

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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