Standard operating procedure (SOP) · FRT-SOP-004 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 8.7

At a glance

- Each adverse event, including ovarian hyperstimulation and procedure complications, is recorded.
- Each event is reviewed by a clinician within the set time.
- Success rates are reported with the basis for the calculation.
- Events are reviewed each quarter.
- Stop and get help straight away if: an adverse event is not recorded or reviewed, or a success rate is published without its basis.

1. Purpose

To find and reduce complications, and to report success rates honestly (8.7).

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

Complications such as ovarian hyperstimulation are rare but serious. Recording and reviewing them, with success rates, shows whether the clinic is safe and honest.

5. Responsibilities

Role	Responsibility	Competence
Clinical director	Owns the review and the reports	Clinician
Treating clinician	Records and reviews each event	Clinician

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. Record.

- Record the event on FRT-REG-003 with its severity and time.

Key point: Every event, however small.

Step 2. Review.

- Review each event within the set time and record the cause and the action.

Key point: A cause and an action.

Step 3. Report.

- Report success rates each year with the number of cycles and the basis for the calculation.

Key point: The basis is always stated.

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
Adverse events reviewed within the set time	100%	Quarterly	Clinical director	Escalate to chief executive
Success rates reported with basis	100%	Yearly	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-003	Adverse event and success rate register	Register

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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