Organisation name Site or unit		STANDARD OPERATING PROCEDURE **Adverse reactions in donors and recipients**	
Document ID	BLD-SOP-005	**Version**	1.0
Status	Blank form, to adapt	**Issue date**	
Review date		**Replaces**	
Owner		**Approved by**	
Signature			

Standards › Standard 5 › Standard operating procedures (SOPs)

Standard operating procedure (SOP) · BLD-SOP-005 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 5.7

At a glance

- Every adverse reaction in a donor or a recipient is recorded.
- Each reaction is investigated by the blood bank and the clinical team together.
- Serious reactions are reported to the national haemovigilance system as required.
- Each investigation has an outcome and an action.
- Stop and get help straight away if: a transfusion reaction is not recorded or investigated.

1. Purpose

To find and stop the causes of reactions, and to report them (5.7).

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

A reaction to a transfusion, in a donor or a patient, is a signal that must be investigated. If reactions are not reported, the same harm happens again.

5. Responsibilities

Role	Responsibility	Competence
Blood bank director	Leads the investigation	Clinician
Responsible clinician	Records the reaction at the bedside	Doctor or nurse

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 reaction at once (HOS-FRM-007), with the unit number and the time.

Key point: At once.

Step 2. Investigate.

- Investigate with the clinical team, and check the unit and the process.

Key point: Both sides investigated.

Step 3. Report.

- Report serious reactions to the national reporting system, and record the report number.

Key point: Reported and recorded.

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
Reactions recorded and investigated	100%	Monthly	Blood bank director	Escalate to governing body
Serious reactions reported	100%	Monthly	Blood bank director	Escalate to governing body

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, in 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
BLD-FRM-003	Adverse reaction report	Report
HOS-FRM-007	Bedside transfusion check and reaction record	Bedside

17. Evidence

Reference	Note
E-009	Based on the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components.
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

19. 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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