

Procedure consent and realistic outcomes

Standard operating procedure (SOP) | PRO-SOP-002

Document type	Standard operating procedure (SOP)
Title	Procedure consent and realistic outcomes
Document ID	{{facility.code}}-PRO-SOP-002
Version and status	1.0 Issued for use. Pending ASF Expert Committee ratification
Prepared by	{{roles.quality_lead.name}}, Quality lead
Reviewed by	{{roles.clinical_director.name}}, Clinical director Date: _____
Approver and signature	{{roles.clinical_director.name}}, Clinical director Signature: _____ Date: _____
Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	None (new document)
Standards and criteria supported	Standard 11 (Procedure Units), criterion 11.4
Evidence basis	E-006, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. Consent is informed and recorded on PRO-FRM-003 before each procedure.
2. It covers the expected outcome, the risks, the complications that can occur and their treatment, and the alternatives.
3. For elective procedures the patient has time to reconsider, and the time given is recorded.
4. Results are given realistically, not as guarantees.

Stop and get help straight away if: a procedure starts without consent that covers the risks and complications, or an elective patient is pushed to decide without time to reconsider.

1. Purpose

To give each patient realistic information and time to decide (11.4).

2. Scope

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

3. Definitions and abbreviations

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

4. Background and rationale

Consent for a procedure must cover what can go wrong, not only what is expected. A patient who did not hear about the risks cannot make a real decision.

5. Responsibilities

Role	Duties in this SOP	Competence needed
Responsible practitioner	Gives the information and records consent	Clinician
Nurse	Confirms the reconsideration time is recorded	Nurse

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Records and forms named in this document	Current version	Checked before use

7. Safety and infection prevention

- 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

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Inform.	Explain the expected outcome, risks, complications and their treatment, and alternatives, using PRO-FRM-003.	Realistic, complete.
2	Give time.	For elective procedures, give a defined time to reconsider, and record the date and time given.	Time to decide.
3	Record.	Record the consent, the questions asked and the answers.	Recorded before the procedure.

Decision points

- No decision points in this procedure.

10. Special situations

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

11. Problems and escalation

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

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Consent records covering risks and complications	100%	Monthly	Medical director	Escalate to chief executive

13. Records

Record	Where it is kept	Kept for
Record named in this document	Patient record or the area file	{{facility.records_retention_years}} years

14. Training and competence

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

15. Related documents

ID	Title	Relationship
PRO-FRM-003	Procedure consent and reconsideration record	Record
CON-SOP-001	Informed consent before significant care (existing, reused)	Procedure

16. Evidence

ID	Source and status
E-009	Based on the ASF Expert Committee consensus and the WHO Guidelines for Safe Surgical Care and Safe Procedures (2009).
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Pending Expert Committee approval