

Informed Consent Before Significant Care

Standard operating procedure (SOP) | CON-SOP-001

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Title	Informed Consent Before Significant Care
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Prepared by	{{roles.quality_lead.name}}, Quality lead
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Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	Replaces the earlier short form
Standards and criteria supported	Standard 1, criterion 1.3 (non-negotiable)
Evidence basis	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. Confirm the procedure needs written consent (see the list in the clinical policy).
2. Explain the diagnosis, the procedure, its benefits, risks, alternatives, and what happens if the patient says no.
3. Check the patient understands, by asking them to explain it back in their own words.
4. Use an interpreter if the patient does not understand the language used.
5. Record consent on CON-FRM-001 with a witness, before the procedure starts.

Stop and get help straight away if: the patient does not understand, has not been given the information, is pressed to decide, asks to stop, or no interpreter is available when one is needed.

1. Purpose

To make sure every patient decides about significant care with the information they need, in a way they understand, and that the decision is recorded before the care starts [EC].

2. Scope

Applies to	All clinicians who propose or carry out procedures and treatments, and staff who witness consent
Locations	All clinical areas at {{facility.legal_name}}
When	Before any procedure that is invasive, carries significant risk, involves sedation or anaesthesia, uses high-risk medicines, or changes the body in a lasting way, as listed in the clinical policy
Does not apply to	Emergency treatment where delay would cause serious harm and the patient cannot consent; section 10 applies

3. Definitions and abbreviations

Term	Meaning in this SOP
Informed consent	A decision by a patient with capacity, based on information about the procedure, its benefits, risks and alternatives, given freely
Capacity	The ability to understand the information, retain it, weigh it up, and communicate a decision
Material risk	A risk that a reasonable patient would want to know before deciding
Witness	A member of staff, not the person doing the procedure, who sees the patient sign or confirm consent
Legal representative	A person authorised by law to decide for a patient who lacks capacity

4. Background and rationale

Consent is both a legal and an ethical requirement. It is the means by which a patient exercises control over their own care. Records of consent are the evidence that the process took place.

This SOP is the method for criterion 1.3: one consent record per sampled patient, anonymised for audit. The consent form set (SOP-118) is used as the record.

5. Responsibilities

Role	Duties in this SOP	Competence needed
Clinician performing the procedure	Gives the information, checks understanding, obtains and records consent	Competent in the procedure and in consent conversations
Witness	Confirms the patient signed or confirmed consent, and signs the record	Trained in this SOP
Ward or department head	Checks consent records before scheduled procedures; supports staff	Management training
Interpreter (if used)	Interprets accurately and does not add or remove information	Qualified or accredited interpreter (SOP-041)

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Consent record (CON-FRM-001)	Current version; patient identifiers filled in	Version and identifiers correct
Procedure information leaflet	Plain language, in the patient's language where available	Current version
Pen	Permanent ink	Working

7. Safety and infection prevention

- Use a private space for the conversation where possible.
- Do not start any part of the procedure, including sedation or site marking, until consent is recorded.
- Keep the consent record with the medical record.

8. Before you start

- Check the procedure needs consent using the clinical policy list.
- Check who will carry out the procedure and who the patient can ask for more information.
- Check whether an interpreter is needed and book one if so.
- Check whether the patient has a legal representative or a previous advance decision in their record.

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	Introduce yourself and the purpose of the conversation.	• Give your name and role. • Say what procedure is planned and why it is needed. • Ask the patient how they would like the information (full detail, or summary and questions).	The patient controls how much they hear. Some people want detail, some want the outline first.
2	Give the information.	• Explain the diagnosis and the reason for the procedure in plain language. • Describe what will happen, who will do it, and how long it takes. • Explain the benefits and the material risks, with the likelihood where known. • Explain the alternatives, including no treatment, and what happens if the patient declines. • Give the leaflet and say where to find more information.	Use everyday words. Avoid jargon. Give numbers where you have them, and say when you do not know.
3	Check understanding (teach-back).	• Ask the patient to explain in their own words what will happen and what the main risks are. • If the explanation is incomplete, repeat the missing part and ask again. • Ask whether they have any questions, and answer them.	Teach-back is the test that the information was understood, not just given.
4	Confirm the patient has capacity.	• Check the patient can understand, retain, weigh up the information, and communicate a decision. • If capacity is in doubt, follow the hospital capacity assessment (EC) and involve the senior clinician. • If the patient lacks capacity, identify the legal representative and follow the legal pathway in section 10.	Capacity is decision-specific. A patient may have capacity for one decision and not another.
5	Confirm the decision and ask the patient to sign or confirm.	• Ask whether the patient agrees to the procedure, declines, or wants more time. • If they agree, the patient signs CON-FRM-001 or confirms verbally in the presence of a witness. • Do not sign on the patient's behalf.	The signature is the patient's own. A witness is needed for verbal consent.
6	Record the consent before the procedure.	• Complete CON-FRM-001: procedure, risks and alternatives explained, interpreter used if any, capacity confirmed, signature or verbal consent with witness, date and time. • File the form in the medical record and check it is present before the procedure starts (the pre-procedure safety check).	If it is not recorded, the procedure should not start.
7	Respect a change of mind.	• Tell the patient they can change their decision at any time, before or during the procedure. • If the patient withdraws consent, stop safely, make the patient safe, and record the withdrawal and the time. • Inform the clinician responsible for the care plan.	Consent is not a one-time event. Stopping safely is part of the procedure.

Decision points

- If the patient understands and agrees, proceed to step 5.
- If the patient understands and declines, record the refusal, explain what care remains available, and inform the responsible clinician.
- If the patient does not understand after teach-back, do not proceed. Give more time or an alternative explanation, and use an interpreter if needed.

10. Special situations

Situation	What to do
Patient who does not share the language of the team	Use a qualified interpreter. Do not use family members as interpreters unless the patient asks and the hospital allows it (EC).
Child or adolescent	Involve the parent or guardian. Involve the child in the discussion at a level appropriate to age (EC).
Patient lacking capacity	Identify the legal representative as set by law. Record the basis for the decision and the person who made it (EC).
Emergency where the patient cannot consent	Follow the emergency treatment rules in the clinical policy. Record the reason and the people involved (EC).
Consent given earlier, but the plan has changed	Repeat the discussion for the new or significant change. Consent for the old plan does not cover new material risks.

11. Problems and escalation

- If the patient is pressured, or the team cannot explain the procedure, pause and inform the responsible clinician.
- If consent is missing when the procedure is due to start, cancel or postpone the procedure and inform the ward head.
- Complaints about consent go to INC-POL-002.

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Consent records complete for sampled patients (anonymised audit of 10 records)	100% (non-negotiable)	Quarterly	Quality lead	Review of each missing record; retraining of the team involved
Procedures started with consent recorded before the start (pre-procedure check)	100%	Monthly	Ward or department head	Stop-and-review of the procedure list; retraining
Patient feedback on understanding of information (sample)	Set by committee	Quarterly	Patient representative	Review of the information leaflets and conversation practice

13. Records

Record	Where it is kept	Kept for
CON-FRM-001 Consent Record	Medical record	{{facility.records_retention_years}} years
Withdrawal of consent (in the record notes)	Medical record	{{facility.records_retention_years}} years

14. Training and competence

- Clinicians are trained in consent conversations and assessed by observation before performing procedures alone (EC).
- Refresher each year, and after any complaint or incident involving consent (EC).
- Witnesses are briefed on their role at induction.

15. Related documents

ID	Title	Relationship
CON-FRM-001	Consent Record	Used in step 5

ID	Title	Relationship
CON-POL-001	Patient Rights and Responsibilities	Patients are told of their right to decide
SOP-041	Interpreter Use Procedure (generic)	Used when the patient needs an interpreter
REC-FRM-001	Mandatory Records List	Consent is a mandatory record entry
INC-POL-002	Complaints and Feedback	Route for consent complaints

16. Evidence

ID	Source and status
E-009	ASF Expert Committee consensus. No published source identified at time of writing. Legal rules checked against national law.

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}}	Full procedure written; added teach-back, capacity steps, withdrawal, special situations	Approved by the ASF Expert Committee