Organisation name Site or unit		STANDARD OPERATING PROCEDURE **Informed Consent Before Significant Care**	
Document ID	CON-SOP-001-EN	**Version**	1.2
Status	To be issued	**Issue date**	
Review date		**Replaces**	1.0
Owner	Clinical lead for this procedure	**Approved by**	
Classification	Internal	**Applies to**	All clinical areas
Signature			

This is a controlled copy when approved. Printed copies are uncontrolled; check the version against the document register before use.

1. Contents

1. Purpose	**2**
2. Scope	2
3. Definitions	2
4. Background	2
5. Responsibilities	3
6. Materials and equipment	3
7. Safety and exceptions	3
8. Procedure	3
9. Worked example	4
10. Decision points	5
11. Escalation	6
12. Monitoring and compliance	6
13. Records	6
14. Training and competence	6
15. Related documents	6
16. References	6
17. Change history	6

Abbreviations	1
Annex A. Consent audit record	7

2. Abbreviations

Abbreviation	Meaning
CON-FRM-001	Consent form
SOP	Standard operating procedure

Key points

- Written consent is obtained before any procedure on the written-consent list in the clinical policy: invasive, high-risk, sedating or anaesthetic procedures.
- Explain the diagnosis, the procedure, its benefits, its risks, the alternatives, and what happens if the patient says no.
- Check understanding by asking the patient to explain it back in their own words.
- Record consent on CON-FRM-001, witnessed, before the procedure starts.
- Stop if the patient does not understand, asks to stop, is pressed to decide, or no interpreter is available when one is needed.

3. 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. Consent is a decision, not a signature: the form records the decision that was made in the conversation.

4. Scope

Element	Coverage
Who	Clinicians who propose or carry out procedures, and staff who witness consent.
Where	All clinical areas at the facility.
When	Before any procedure on the written-consent list, and before any procedure whose risks the clinician judges significant.
Not covered	Emergency care where the patient cannot consent, which is covered by the emergency treatment policy.

5. Definitions

Term	Meaning

Informed consent	A decision made by the patient, having been given the information they need, and having understood it, without pressure.
Capacity	The patient's ability to understand the information, retain it, weigh it, and communicate a decision. Capacity is decision-specific and can change over time.
Witness	A member of staff who saw the consent given and confirms that the patient agreed freely.
Interpreter	A qualified interpreter, in person, by telephone or by video. A family member is not used to interpret for consent.

6. Background

A patient has the right to decide about their own care. A decision made without the information needed, or without understanding, is not informed, and a signature obtained under pressure is not consent. Recording the decision before the procedure makes it visible and protects both the patient and the clinician.

7. Responsibilities

Role	Responsibility
Clinical director	Approves this SOP and the written-consent list, and receives the quarterly audit.
Clinician proposing the procedure	Explains the procedure, checks understanding, answers questions, and obtains consent.
Witness	Confirms that the consent was given freely, and signs the form.
Interpreter service	Provides a qualified interpreter when one is needed.

8. Materials and equipment

Item	Requirement
Consent form CON-FRM-001	The current approved version.
Written information	Information about the procedure in the patient's language, where available.
Interpreter access	In-person, telephone or video, arranged in advance for planned procedures.

9. Safety and exceptions

- Capacity. Where the patient may lack capacity for this decision, assess it using the facility's capacity policy, and do not proceed on the basis of this SOP alone.
- Time to decide. Where the procedure is not urgent, give the patient time to consider and to talk to family. Do not press them to decide on the same day unless the clinical situation requires it.

- Change of mind. The patient can withdraw consent at any time before the procedure. Record the withdrawal and inform the clinician.

10. Procedure

Before you start

- Confirm from the written-consent list that written consent is required.
- Check that an interpreter is booked, or is available now, if the patient needs one.
- Check that the witness is available before the consent discussion.

Step 1. Explain

- Say what the diagnosis is, in plain language, and what the procedure will involve, step by step.
- Explain the benefits, the risks (including the common and the serious), the alternatives (including doing nothing), and what happens if the patient says no.
- Give written information where available, and give the patient time to ask questions.

Step 2. Check understanding

- Ask the patient to explain the procedure back in their own words, including one risk and one alternative.
- Where the explanation is incomplete, repeat the missing part and ask again. Record that the explanation was checked.
- If the patient still does not understand, do not proceed. Consider an interpreter, a different time, or a different format.

Step 3. Record the decision and witness

- Record the patient's decision on CON-FRM-001, with the date and the time.
- Obtain the witness's signature before the procedure starts. The witness confirms that they saw the patient agree freely.
- Record whether an interpreter was used, and who provided it.

11. Worked example

Situation	What to do
A patient is to have a central venous line. He speaks limited English and his daughter offers to translate.	Do not use the daughter to interpret for consent. Book a qualified interpreter (in person, telephone or video). Explain the procedure with the interpreter, check understanding through the interpreter, and record the interpreter's name or identifier on CON-FRM-001. If an interpreter is not available in time, postpone the procedure if it is not urgent.
A patient says yes to a biopsy, and then says, while being prepared, that she wants to stop.	Stop. Respect the withdrawal, do not proceed, record the withdrawal and the time, and inform the clinician.

Figure 1. Consent pathway

12. Decision points

If	Then
Patient understands and agrees	Record consent with a witness, then proceed.
Patient does not understand	Explain again; use an interpreter if needed; do not proceed.
Patient declines	Respect the decision; record it; explain the consequences.
Patient may lack capacity	Follow the capacity policy; do not proceed on this SOP alone.
Interpreter not available when needed	Postpone the procedure, if not urgent, and escalate.

13. Escalation

Event	Inform	Timescale
Procedure started without recorded consent	Clinician in charge and risk team	Immediately; incident report within 24 hours
Patient pressed to decide, or asks to stop	Clinician in charge	Immediately
No interpreter for a patient who needs one	Unit manager and interpreter service	Same shift

14. Monitoring and compliance

Indicator	Target	Method	Frequency	Owner
Listed procedures with signed consent and witness before start	100% of listed procedures	Audit of 20 records per unit	Quarterly	Clinical lead
Interpreter use recorded where needed	100% of cases needing one	Audit of records	Quarterly	Unit manager

15. Records

Record	Kept in	Retention
Consent form CON-FRM-001	Patient record	As set by the institutional retention policy

16. Training and competence

- Induction: the consent conversation, the teach-back check, capacity, and working with interpreters. Competence is assessed by observed consent conversations.

- Annual update: audit of consent records and a case review.

17. Related documents

ID	Title	Relationship
CON-SOP-001-EN	Informed Consent Before Significant Care	This SOP

18. References

ASF Expert Committee decision on the consent process. No external clinical guideline was cited. The list of procedures requiring written consent is defined in the facility's clinical policy and must be confirmed by the clinical director; the capacity policy applies where capacity is in question.

19. Change history

Version	Date	Summary of change	Approved by
1.0		First approved version.	ASF Expert Committee
1.2		Substantive revision: explanation content, teach-back, capacity, interpreter rule, withdrawal of consent, and worked examples.	

20. Annex A. Consent audit record

Use this record for each audit session. Record one line per patient or task observed. Enter Y, N or NA as shown in the column heading.

Date	Unit	Patient reference	Procedure on the written-consent list (Y / N)	Consent signed before start (Y / N)	Witness signed (Y / N)	Interpreter used or not needed (Y / N / NA)	Comment