Standard operating procedure (SOP) · AI-SOP-002 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2D.6

At a glance

- Consult the staff who will use an AI system before the decision is final.
- Ask about practical impact, workload and training needs.
- Address the training needs before go-live.
- Record the consultation on AI-FRM-002.
- Stop and get help straight away if: an AI system goes live with no consultation record.

1. Purpose

To make sure staff who will deliver care with an AI system understand its practical effect, raise their concerns, and are trained before go-live [EC].

2. Scope

Applies to	Clinical project lead, staff who will use the system, staff representatives
Locations	Each clinical area that will use the system
When	Before the decision is final, and before go-live
Does not apply to	Staff who never use the system

3. Definitions

Term	Meaning
Consultation	A two-way discussion in which concerns are heard and answered, recorded before the decision
Training need	A skill or knowledge gap identified before use

4. Background

A system introduced without staff input often fails in practice, through workload, unclear use or lost trust. Criterion 2D.6 asks for consultation before introduction.

5. Responsibilities

Role	Responsibility	Competence
Clinical project lead	Runs the consultation and records it	Clinical
Staff representatives	Raise concerns on behalf of teams	Staff
Chief executive	Takes the final decision with the consultation record	Executive

6. Materials and equipment

Item	Requirement	Condition
Consultation record (AI-FRM-002)	Current	Completed for each system
Briefing summary on the system	Plain language	Given to staff before the session

7. Safety

- Staff concerns about patient safety must be recorded and answered before go-live, not after.

8. Before you start

- Prepare a plain-language summary of the system.

9. Procedure

Step 1. Brief staff.

- Explain the system, its purpose, what it does and does not do, and who uses it.

Key point: Plain language, not technical marketing.

Step 2. Consult.

- Hold sessions with each staff group who will use the system.
- Record each concern, question and response.

Key point: Record the concern even if it cannot be fixed. Explain why.

Step 3. Identify training needs.

- List the skills needed and the training method for each group.

Key point: Training is part of the consultation, not an add-on.

Step 4. Respond before go-live.

- Respond to each concern in writing before go-live.
- Address training before any staff use the system.

Key point: A concern without a response is a reason for staff to ignore the system.

Step 5. Ask after go-live.

- Ask staff about the system after three months, and record the result.

Key point: Only use reveals the real effect.

10. Decision points

- If a concern about patient safety is not resolved, go-live is delayed until the chief executive decides.

11. Special situations

Situation	Action
Urgent introduction	Consult as far as possible in the time available, and complete the record afterwards within 14 days.

12. Escalation

- Unresolved safety concerns go to the chief executive.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Systems with consultation record before go-live	100%	Each system	Clinical project lead	Stop go-live
Training completed before use	100%	Each system	Clinical project lead	Delay use
Staff who can describe the consultation (sample)	At least 80% (EC)	Yearly	Clinical lead	Re-brief

14. Records

Record	Kept in	Retention
AI-FRM-002 Staff Consultation Record	Governance file	the period set by the facility’s records policy years

15. Training

- Project leads are trained in consultation methods (EC).

16. Related documents

ID	Title	Use
AI-FRM-002	Staff Consultation Record	Used in steps 2 to 4
AI-POL-001	Responsible Use of AI in Care Policy	Parent policy
SOP-N29	Learning, Training and Competence Policy (generic)	Training and competence

17. Evidence

Reference	Note

E-011	WHO (2021), Ethics and governance of artificial intelligence for health. Used as the basis for AI governance. Link and wording to verify before publication.
E-009	ASF Expert Committee consensus. Consultation method to be agreed.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	Approved by the ASF Expert Committee
1.1	the date of approval	Internal quality review: corrected cross-references, status wording and document control	Approved by the ASF Expert Committee

E-learning for this document

- **Artificial Intelligence in Healthcare Safety** (AI-001)

References

- Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)
- World Health Organization (2021). Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: WHO. **Open source** (E-011)

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