	DOCUMENT NAME	DOCUMENT NUMBER
	INFORMED CONSENT PROCESS	

VERSION	**1**	
COMPILED BY		**DATE**
AUTHORIZED BY		**07/2025**
NEXT REVISION DATE		**07/2027**

1. PURPOSE & SCOPE

To ensure that all users of healthcare services are provided with sufficient, relevant, and understandable information before giving voluntary and informed consent to medical interventions, in accordance with Section 7 of the National Health Act (Act 61 of 2003).

This procedure applies to all healthcare personnel involved in providing treatment, performing diagnostic tests, procedures, or surgeries at [Insert Practice Name].

2. RESPONSIBILITIES

Job description of person responsible	Duties

3. DEFINITIONS

Informed Consent: Voluntary agreement to a medical intervention by a user who has received and understood all relevant information.

User: The person receiving health services.

Legal Representative: Parent, guardian, spouse, or proxy where the user is a minor or unable to consent

4. PROCEDURE

Required Information to be Disclosed

The healthcare provider must explain the following, verbally and in writing where necessary:

Information	Details
Nature of the condition	Diagnosis, including any uncertainty
Purpose of the intervention	What the proposed procedure or treatment aims to achieve
Risks and benefits	Common and serious risks, benefits, and side effects
Alternatives	Available alternative treatments or interventions
Prognosis	What to expect with or without the intervention
Costs	Indicative costs (where applicable)
Right to refuse	The user's right to decline or withdraw consent without penalty

Procedure for Obtaining Consent

1. **Pre-Discussion Preparation**
    - Review clinical notes and diagnostic information.
    - Prepare relevant consent forms and information sheets.
2. **Discussion with User**
    - Use language the user understands (include interpreter if needed).
    - Confirm understanding using teach-back methods.
3. **Documentation**
    - Complete the consent form with all details above.
    - Have the user or legal representative sign and date the form.
    - Provider signs the form as a witness.
    - Store the form in the user's health record (manual or electronic).
4. **Special Circumstances**
    - For minors: Obtain consent from legal guardian unless the minor is over 12 and deemed mature.
    - In emergencies: Proceed without consent if delay risks life/health, as per Section 7(1)(c).
    - If user lacks capacity: Follow legal protocols to involve a legal representative.

5. Storage and Retention of Consent Forms

- All signed consent documents must be stored securely in the health record system.
- Retain according to record retention guidelines (minimum 6 years, or until child turns 21, whichever is later).

6. Monitoring and Audit

- Quarterly audits of patient files to verify presence and completeness of informed consent documentation.
- Non-compliance reported to clinical governance team.

7. Training

- All health care providers must receive induction and annual refresher training on informed consent protocols.

8. References

- National Health Act 61 of 2003, Section 7
- HPCSA Guidelines – Booklet 9: Guidelines on Patient Records
- POPI Act – Confidentiality obligations

5. INTERNAL SUPPORTING DOCUMENTATION

Document	Number	Retention period	Location

6. ATTACHMENT

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Receipt Acknowledgement for this SOP

I have read and been informed about the content, requirements, and expectations of this policy for this practice. I understand that if I have questions, at any time, regarding this policy, I will consult with my immediate supervisor or my Human Resources staff members. Please read the policy/procedure carefully to ensure that you understand the policy/procedure before signing this document.

Employee Signature	Employee Printed Name	DATE	Employee Signature	Employee Printed Name	DATE