

SOP Template: Confirmation of Informed Consent Requirements per Treatment/Service

This SOP details the process for **confirmation of informed consent requirements** per treatment or service, ensuring that patients receive comprehensive information about the nature, benefits, risks, and alternatives of the proposed interventions. It covers verifying patient understanding, documenting consent appropriately, and adhering to legal and ethical standards to protect patient autonomy and maintain trust in healthcare delivery.

1. Purpose

To establish a standardized procedure for confirming and documenting informed consent prior to performing any treatment or service.

2. Scope

This SOP applies to all healthcare providers involved in the delivery of treatments and services requiring informed consent.

3. Responsibilities

- Healthcare providers must explain the treatment, alternatives, risks, and benefits to patients.
- Staff responsible for documenting and filing consent forms.
- Supervisors monitor adherence to consent protocols and provide ongoing training.

4. Procedure

1. **Identify Consent Requirement:** Determine if the planned intervention requires written or verbal informed consent according to institutional policy and law.
2. **Provide Information:**
 - Explain the **nature and purpose** of the treatment/service.
 - Discuss **potential benefits and risks**, including common and serious side effects/complications.
 - Present **alternative options** (including no treatment) and respective risks/benefits.
3. **Assess Understanding:** Use teach-back or open-ended questions to confirm that the patient comprehends the information provided.
4. **Obtain Consent:** Ensure the patient voluntarily agrees to proceed. Use officially approved consent forms where applicable.
5. **Document Consent:**
 - Complete and sign the informed consent form, including relevant details (date, time, names of those present).
 - For verbal consent, document key details in the medical record.
6. **File Documentation:** Upload consent forms to the patient's record and retain according to record-keeping policies.

5. Special Considerations

- For minors or incapacitated patients, obtain legal guardian or representative consent per local regulations.
- Use interpreter services for non-native speakers or patients with communication barriers.
- Repeat the consent process if the patient's condition or the proposed intervention changes.

6. References

- Institutional consent policies and relevant legal/regulatory frameworks
- Professional guidelines (e.g., AMA, WHO)