

# SOP Template: Patient Consent Acquisition and Documentation

This SOP details the process for **patient consent acquisition and documentation**, encompassing the identification of patients, explanation of procedures and treatments, assessment of patient understanding, obtaining informed consent through verbal or written methods, and accurate recording and secure storage of consent forms. The objective is to ensure ethical, legal, and regulatory compliance while respecting patient autonomy and promoting clear communication between healthcare providers and patients.

## 1. Purpose

To outline standardized procedures for patient consent acquisition and documentation to ensure ethical, legal, and regulatory compliance while maintaining patient rights and clear communication between healthcare providers and patients.

## 2. Scope

This SOP applies to all healthcare personnel involved in obtaining, documenting, and managing patient consent for medical procedures, treatments, or participation in research activities.

## 3. Responsibilities

- **Healthcare Providers:** Explain procedures, assess understanding, obtain and document consent.
- **Administrative Staff:** Store and manage consent documentation.
- **Supervisors/Managers:** Ensure compliance and provide necessary training.

## 4. Definitions

- **Informed Consent:** Voluntary agreement given by a patient after receiving adequate information regarding the procedure or treatment, potential risks, benefits, and alternatives.
- **Verbal Consent:** Consent given verbally and documented in the patient record by the healthcare provider.
- **Written Consent:** Consent confirmed by the patient's signature on a consent form.

## 5. Procedure

1. **Patient Identification:**
  - Verify patient identity using at least two approved identifiers (e.g., name, DOB, medical record number).
2. **Explanation of Procedure/Treatment:**
  - Clearly explain the proposed procedure/treatment, its purpose, risks, benefits, and alternatives in understandable terms.
  - Allow sufficient time for patient questions and discussion.
3. **Assessment of Understanding:**
  - Ensure the patient comprehends the information provided by asking them to summarize or ask clarifying questions.
4. **Obtaining Consent:**
  - Obtain written consent when required by law or facility policy; otherwise, verbal consent may be accepted and documented.
  - For minors or those lacking capacity, obtain consent from a legally authorized representative.

5. **Documentation:**

- Document the type of consent obtained, date, time, and the name of the consenting individual or representative.
- Include details of information provided to the patient and their expressed understanding.

6. **Storage and Security:**

- Store signed consent forms securely in the patient's medical record (electronic or paper) in compliance with institutional and legal guidelines regarding privacy and data protection.

## 6. References

- Institutional policies and guidelines
- National and regional regulations on patient rights and informed consent
- Relevant professional codes of ethics

## 7. Appendices

- Sample Patient Consent Form
- Checklist for Consent Acquisition

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### Sample Documentation Table

Step	Description	Responsible Party	Documentation Required
Patient Identification	Confirm patient identity using two approved identifiers	Healthcare Provider	Patient record entry
Explanation of Procedure	Describe procedure, risks, benefits, and alternatives	Healthcare Provider	Progress notes, consent form
Assessment of Understanding	Assess patient's understanding of provided information	Healthcare Provider	Progress notes
Consent Acquisition	Obtain written or verbal consent as appropriate	Healthcare Provider	Signed consent form or progress note documentation
Documentation & Storage	Record consent and store securely	Administrative Staff	Medical record update, secure filing