

# SOP Template: Instructions for Obtaining Verbal or Written Consent

This SOP provides detailed **instructions for obtaining verbal or written consent**, ensuring that consent is informed, voluntary, and documented appropriately. It covers the process of explaining relevant information clearly to the consenter, verifying understanding and willingness, specifying when verbal or written consent is required, and proper record-keeping to maintain compliance with legal and ethical standards. The purpose is to safeguard the rights and autonomy of individuals by implementing standardized consent procedures.

## 1. Purpose

To provide standardized procedures for obtaining, documenting, and maintaining verbal or written consent in compliance with ethical and legal guidelines.

## 2. Scope

This SOP applies to all personnel responsible for obtaining consent in research, clinical, or operational activities requiring verbal or written consent.

## 3. Responsibilities

- Ensure that individuals providing consent are fully informed in clear, understandable language.
- Verify the understanding and voluntariness of consent.
- Properly document and store records of obtained consents.

## 4. Procedure

### 4.1 Preparation

1. Review relevant study, project, or procedure information.
2. Prepare consent forms and supporting materials.
3. Ensure privacy and adequate time for the consent process.

### 4.2 Providing Information

1. Explain the purpose, procedures, risks, benefits, and alternatives in clear, non-technical language.
2. Be open to questions and clarify all concerns.
3. Offer information both verbally and, where appropriate, in written form.

### 4.3 Assessing Understanding

1. Ask the consenter to summarize their understanding or answer key questions.
2. Address any misunderstandings or additional questions.

### 4.4 Obtaining Consent

- **Written Consent:**
  1. Present the consent form and allow the individual to review.
  2. Obtain signatures and dates from all parties.
  3. Provide a copy to the consenter.
- **Verbal Consent:**
  1. Verbally confirm understanding and willingness.
  2. Document consent in the record, noting the date, time, content of the discussion, and names of all present.
  3. Include a witness, when possible.

### 4.5 Documentation and Record-Keeping

1. Securely store written consent forms and documentation of verbal consents.
2. Maintain confidentiality and limit access to authorized personnel only.
3. Record all consent activities in accordance with organizational and legal requirements.

## 5. When to Use Verbal vs. Written Consent

- **Written consent** must be used for high-risk or legally required situations.
- **Verbal consent** may be used for minimal risk activities or where written consent is impractical, with adequate documentation.

## 6. Compliance and Review

1. Review this SOP annually or as regulations change.
2. Report any deviations or concerns to the appropriate authority/ethics board.

## 7. References

- Applicable organizational policies
- Relevant legal or regulatory guidelines
- Ethics board requirements