

Standard Operating Procedure (SOP)

Procedure for Retrieving, Updating, or Rescinding Consent

This SOP defines the steps involved in the **procedure for retrieving, updating, or rescinding consent**, ensuring compliance with legal and ethical standards. It outlines how to properly document initial consent, the methods to update consent when circumstances change, and the process for safely rescinding consent upon request. The purpose is to maintain clear communication, protect individual rights, and uphold data privacy by managing consent records effectively throughout their lifecycle.

1. Purpose

To establish standardized procedures for documenting, retrieving, updating, and rescinding consent, in compliance with legal, ethical, and institutional requirements.

2. Scope

This SOP applies to all staff responsible for handling consent processes, including but not limited to research, clinical, or data processing activities where consent is required.

3. Responsibilities

- **Staff:** Ensure all consent interactions adhere to this SOP.
- **Managers/Supervisors:** Oversee compliance and provide necessary training.
- **Data Protection Officer:** Ensure that procedures uphold current data privacy regulations.

4. Definitions

- **Consent:** The informed, voluntary agreement by an individual to participate or allow use of their data for a specific purpose.
- **Update:** Modifying previously granted consent to reflect new terms or information.
- **Rescind:** Officially withdrawing consent.

5. Procedure

1. Documenting Initial Consent

- a. Provide clear, comprehensive information to the individual regarding the consent.
- b. Record consent using approved forms (electronic or paper), capturing:
 - Individual's name and contact information
 - Date and time of consent
 - Method of consent (written, verbal, digital)
 - Specifics of what is being consented to
- c. Securely store consent records in a designated system accessible only to authorized staff.

2. Retrieving Consent

- a. Access the consent database or physical archive as needed.
- b. Verify requester's authorization before disclosing any consent information.
- c. Provide a copy or summary of the consent record as appropriate.

3. Updating Consent

- a. Inform the individual of changes requiring an update to consent.
- b. Document revised consent details, including:
 - Date, time, and reason for update
 - New terms and individual's acknowledgment
- c. Replace or append updated documents to original consent record, ensuring an audit trail is maintained.

4. Rescinding Consent

- a. Receive and verify the request to rescind consent (written or verbal, per policy).
- b. Document date, time, and reason for rescindment, if provided.
- c. Immediately cease all activities covered by the consent.
- d. Notify relevant personnel of the rescinding of consent.
- e. Update records to reflect rescindment and archive appropriately.

6. Documentation and Recordkeeping

- All consent records must be maintained securely and confidentially.
- Maintain an audit trail of updates or rescindments to consent.
- Retention periods for records shall comply with applicable regulations and institutional policies.

7. Compliance and Review

- All procedures are subject to periodic review to ensure ongoing compliance and improvement.
- Non-compliance must be reported to the Data Protection Officer or equivalent authority.

8. References

- Applicable laws (e.g., GDPR, HIPAA)
- Institutional Data Privacy and Security Policies
- Ethical Guidelines for Consent

9. Revision History

Date	Version	Description of Change	Author
2024-06-15	1.0	Initial SOP template created	Compliance Team