Standard Operating Procedure (SOP)

Consent Form Distribution and Signature Collection

This SOP details the process for **consent form distribution and signature collection**, covering the preparation, dissemination, tracking, and secure storage of consent documents. It ensures all participants receive, understand, and sign forms in a timely manner, maintaining compliance with legal and regulatory requirements while safeguarding personal information and facilitating efficient record management.

1. Purpose

To outline standardized procedures for distributing consent forms, collecting signatures, and securely tracking and storing signed documents in accordance with regulatory and organizational requirements.

2. Scope

This SOP applies to all personnel involved in preparing, disseminating, collecting, and storing consent forms for research, service, or other purposes within [Department/Organization Name].

3. Responsibilities

- **Study/Project Coordinator:** Oversees consent form preparation and overall process management.
- **Designated Staff:** Distributes forms, provides explanations, ensures understanding, and collects signatures.
- **Principal Investigator (PI)/Manager:** Ensures compliance with applicable policies and regulations.
- **Data/Records Manager:** Secures and archives signed documents.

4. Procedure

1. **Preparation of Consent Forms:**
    - Verify the latest approved version of the consent form is available, including all necessary information (purpose, risks, rights, contact information, etc.).
    - Prepare sufficient copies for all prospective participants (hard copy or electronic).
    - Obtain ethical/regulatory approvals if required.
2. **Distribution of Consent Forms:**
    - Provide each participant with the consent form prior to any related activity.
    - For in-person distribution, hand the form directly to the participant and allow adequate reading time.
    - For electronic distribution, ensure secure delivery (e.g., encrypted email, secure portal).
    - Maintain a log of all distributed forms (including date, participant, and method of distribution).
3. **Explanation and Clarification:**
    - Offer to answer any questions and clarify information.
    - Verify participant comprehension (use teach-back method, if appropriate).
4. **Signature Collection:**
    - Request participant signature and date on the consent form (physical or digital signature, as approved).
    - Where applicable, ensure a witness/co-signer is present and signs the form.
    - For remote collection, use compliant e-signature solutions that meet organizational and legal standards.
5. **Tracking and Documentation:**
    - Record the collection of each signed consent form in a tracking log (including participant name, date, and form version).
    - Verify completeness (all required signatures and dates present).

6. **Storage and Security:**
    - Store signed consent forms in a secure, access-controlled environment (locked cabinets for hard copies, encrypted databases for electronic files).
    - Limit access to authorized personnel only.
    - Back up electronic files regularly and maintain for the required retention period.
    - Dispose of expired records according to data retention/destruction policies.

5. References

- [Regulatory Standard/Guideline, e.g., HIPAA, GDPR, Institutional Policy]
- [Data Retention and Security Policy]
- [Relevant Organizational Policies]

6. Revision History

Version	Date	Description of Change	Approved By
1.0	[Date]	Initial release	[Name/Title]