

SOP Template: Permission and Consent Form Management

This SOP details the processes for **permission and consent form management**, including the creation, distribution, collection, verification, and storage of consent forms. It ensures compliance with legal and organizational requirements, protects individual rights, and maintains accurate records for auditing and accountability. The procedure promotes transparency and clarity in obtaining informed consent for various activities and services.

1. Purpose

To establish standardized procedures for the management of permission and consent forms, ensuring informed consent is properly obtained, documented, and securely maintained.

2. Scope

This SOP applies to all staff responsible for requesting, processing, and managing consent forms for activities or services that require explicit permission from individuals or their legal representatives.

3. Responsibilities

- **Form Originator:** Creates and updates consent form templates as per legal and policy requirements.
- **Distributors:** Disseminate consent forms to relevant participants.
- **Collectors:** Receive and check returned consent forms for completeness and validity.
- **Verifiers:** Ensure forms are correctly filled and signatures are authentic.
- **Records Management Staff:** Store, protect, access, and dispose of forms securely.

4. Procedure

1. **Creation of Consent Forms:**
 - Draft forms using legally-approved templates.
 - Customize content for specific activities, ensuring clarity and plain language.
 - Review and approve by legal or compliance team.
2. **Distribution:**
 - Distribute by paper or secure electronic means.
 - Include clear instructions, deadlines, and contact details for queries.
3. **Collection:**
 - Gather signed forms by designated deadline.
 - Track receipt and follow up on any missing forms.
4. **Verification:**
 - Check forms for accuracy, completeness, and authentic signatures.
 - Flag and resolve discrepancies or incomplete forms.
5. **Storage:**
 - Log each verified form in the forms management register.
 - Store physical forms in secure location; digital forms in a password-protected system.
 - Retain forms for the period specified by legal and organizational policies.

5. Documentation and Recordkeeping

- Maintain a consent form register with details of name, date, activity/service, and form status.
- Ensure access is restricted to authorized personnel only.
- Document any updates, replacements, or revocations of consent.

6. Confidentiality and Security

- Protect all information in consent forms against unauthorized access or disclosure.
- Dispose of forms securely when retention period expires (e.g., shredding, secure deletion).

7. Auditing and Compliance

- Conduct periodic reviews of consent form processes, records, and storage systems.
- Address non-compliance promptly with corrective actions.
- Retain audit logs for traceability.

8. References

- Applicable laws and regulations (e.g., GDPR, HIPAA, local consent laws)
- Organizational policies on data protection and records management

9. Revision History

Version	Date	Description	Author
1.0	2024-06-20	Initial release	[Author Name]