SOP: Consent Form Signing and Documentation Protocol

This SOP details the **consent form signing and documentation protocol**, covering the procedures for obtaining informed consent, ensuring client understanding, proper documentation practices, secure storage of consent forms, and compliance with legal and regulatory requirements. The goal is to maintain clear, accurate, and verifiable records of consent to protect both the organization and individuals involved while facilitating transparent communication and ethical standards.

1. Purpose

To establish standardized procedures for obtaining, documenting, and securely storing informed consent to comply with ethical, legal, and regulatory obligations.

2. Scope

This protocol applies to all staff members involved in activities requiring client/patient/participant consent within the organization.

3. Responsibilities

- **Authorized Personnel:** Responsible for presenting consent forms, addressing questions, and obtaining signatures.
- **Supervisors/Managers:** Ensure staff are trained and protocols are followed.
- **Records/Compliance Officer:** Oversee documentation and secure storage; conduct periodic audits.

4. Procedure

1. **Preparation**
    - Confirm the latest version of the consent form is used.
    - Ensure understanding of the procedure, risks, and benefits to be explained.
2. **Obtaining Informed Consent**
    - Present the consent form to the individual in a language they understand.
    - Review all sections verbally and answer any questions.
    - Assess the individual's understanding using teach-back or comprehension questions.
    - Verify voluntary participation; confirm no coercion or undue influence.
3. **Form Completion and Signing**
    - Ensure the form is filled out completely: date, printed names, signatures of both the consenting individual and authorized staff.
    - If applicable, obtain witness signature.
    - Provide a copy to the individual and retain the original for records.
4. **Documentation**
    - Record the consent process in the individual's file (date, personnel involved, key points discussed).
5. **Secure Storage**
    - Store signed consent forms in a locked file cabinet or password-protected electronic system with

restricted access.
    - Maintain confidentiality in accordance with data protection regulations (e.g., HIPAA, GDPR).

6. **Retention and Disposal**
    - Retain consent forms for the period required by law/regulation (specify duration).
    - Dispose of expired records securely (e.g., shredding, permanent deletion).

7. **Auditing and Compliance Monitoring**
    - Conduct regular audits to ensure completeness and compliance.

5. References

- Applicable federal/state/local regulations (e.g., HIPAA, GDPR)
- Organizational policies on privacy and record-keeping
- Ethical standards for informed consent

6. Revision History

Version	Date	Description	Author
1.0	2024-06-23	Initial SOP template created	[Your Name]