Standard Operating Procedure (SOP)

Participant Registration and Consent Form Collection Process

This SOP details the **participant registration and consent form collection process**, covering steps for verifying participant eligibility, distributing and explaining consent forms, obtaining informed consent, securely collecting and storing signed documents, and ensuring compliance with ethical standards and data protection regulations. The goal is to facilitate a smooth registration experience while safeguarding participants' rights and privacy throughout the study or event.

1. Purpose

To outline standardized procedures to ensure all participants are eligible, informed, and their consent forms are properly handled in compliance with ethical, legal, and data protection standards.

2. Scope

This SOP applies to all staff involved in participant registration and consent form management for the study/event.

3. Responsibilities

- **Registration Staff:** Verify eligibility, guide participants, distribute and explain forms, collect completed documents.
- **Study Coordinator:** Oversee process compliance and secure document storage.
- **Data Protection Officer (if applicable):** Ensure compliance with data privacy regulations.

4. Procedure

1. **Participant Eligibility Verification**
    - Request and review necessary identification and documentation.
    - Confirm eligibility as per protocol inclusion/exclusion criteria.
2. **Consent Form Distribution and Explanation**
    - Provide the latest approved consent form to participant.
    - Clearly explain study/event purpose, procedures, risks, benefits, and participant rights.
    - Address participant questions and allow ample time for consideration.
3. **Obtaining Informed Consent**
    - Confirm participant's comprehension and voluntary agreement.
    - Ensure participant (and/or legally authorized representative) signs and dates the consent form.
    - Countersign and date form as a witness, if required.
4. **Form Collection and Secure Storage**
    - Review completed forms for accuracy and completeness.
    - Assign unique participant ID and log receipt in registration database.
    - Store signed forms in a secure, access-controlled location (e.g., locked cabinet or encrypted digital system).
5. **Compliance and Confidentiality**
    - Ensure all personal data is handled in line with data protection laws (e.g., GDPR, HIPAA).
    - Maintain confidentiality and restrict access to authorized personnel only.

5. Documentation

- Completed and signed consent forms.
- Participant eligibility verification records.
- Registration and consent logs/databases.

6. Review and Revision

This SOP should be reviewed annually or when relevant regulations or protocols change.