Written Standard Operating Procedures provide workers with the operational information necessary to perform a job properly and ensure consistency in the operations. Standard Operating Procedures provide a historical record of steps in the how, why and when and serve as a training tool for teaching users.

How to write your research site’s Standard Operating Procedures:

- Begin by identifying a purpose or a mission statement. Identifying the purpose of your SOP’s will help to focus your energy and set limitations on the necessary content.

- Create an outline of what is actually done on a day to day basis. The individual(s) actually performing the task on a regular basis may be the person(s) best qualified to write that SOP.

- After an outline of the SOP content has been developed, the structure of the SOPs must be developed. It is important to design your SOPs to achieve specific results.
  Possible design options:
  - Simple steps
  - Hierarchical steps
  - Graphic procedures

  SOPs require establishment of procedure codes and topics. It is important to use words such as “will” or “shall” to describe procedural steps. It is best to avoid words such as “should,” “could,” and “may.” These words convey a sense of option. SOPs are not optional.

- A first draft should then be written and distributed for internal review. Any necessary modifications to procedures can be at this time. This will aid in creating a sense of ownership of the document and encourage workers to follow the procedures.

- The final version of the SOPs should then be distributed for external review and tested in practice.

- The SOPs must then be signed for approval and posted. All employees should be trained on the SOPs. This training should be documented.

- The SOPs will be reviewed annually or as needed. Amended SOPs will be distributed to the users and old versions will be destroyed. Archival copies of the SOPs should be maintained by the principal investigator or office manager. Copies of current SOPs should be available in all areas and at each work site where procedures are to be performed.
Guidelines for Writing Standard Operating Procedures (SOP)

The following is an example of the content necessary for a clinical research site’s SOPs.

1.0-GE General SOPs
2.0-SS Study Start-Up (Site Qualification through Initiation)
3.0-PM Project management (Initiation through Termination)
4.0-SM Subject Management (Screening through Completion)
5.0-DM Data Management
6.0-QA Quality Assurance (Sponsor, Institutional, Site, FDA, etc.)

**Purpose:**

To provide guidelines for preparing Standard Operating Procedures (SOPs).

**GE: General**

1.1 GE- Development and Implementation of SOPs
    How you developed your SOPs. Include: SOP sequence coding, format, sign off, dissemination

1.2 GE- SOP Revision

1.3 GE- SOP Training and Orientation (staff training)

1.4 GE- Statement of General Principles
    Include: statement of authority, mission statement for the protection of human subjects, declaration that cGCP is followed.

1.5 GE- Responsibilities of Principal Investigator

1.6 GE- Responsibility of Research Team (with an organizational chart)
    - Subinvestigator
    - Project administrator
    - Research coordinator
    - Data manager
    - Pharmacist
    - Laboratory Director

**SS: Study Start-Up**

2.1 SS- Project Feasibility
    Protocol/Investigator Brochure distribution and assessment
    Dissemination to study staff for comment
Guidelines for Writing Standard Operating Procedures (SOP)

Protocol/IB comment tracking
Final sign off, comments to sponsor
Determine personnel
Identify primary contact
Project time-line review
Meeting: list and clarify ability to carry out trial
File report: Decision to Go/No Go

2.2 SS- Communicating with Sponsor/CRO
Responsibilities
Communication between site/CRO/sponsor
Contacts/reporting

2.3 SS- Site Qualification Visits
Project team identification
Visit preparation
Schedule and coordinate
Prepare regulatory documents
Patient accrual/Project timeline review
Carrying out visit
Follow-up activities

2.4 SS- Institutional Review Board
Regulations
Site specific procedures for review
Organization/Membership
Required documents/forms
Advertisements
Approval tracking

2.5 SS- Informed Consent Development
FDA regulations
Institutional Requirements
Format and Content
Drafting and editing consent document
Final approval/sign-off
Consent Process Guidelines

2.6 SS- Site Initiation Meeting
Pre-meeting preparation
Ancillary services training and participation
Regulatory documentation collection
Patient screening/accrual/tracking
Carrying out meeting
Guidelines for Writing Standard Operating Procedures (SOP)

Post visit responsibilities

2.7 SS- Attending an Investigator Meeting
   Identifying attendees
   Staff responsibilities
   Post meeting

2.8 SS- Project Budgets and Contracts
   Institution procedures
   Sponsor requirements
   Letter of agreement
   Indemnification
   Overhead Budget preparation
   Payment schedule/tracking
   Definition of subject completion (evaluable subjects)

PM: Project Management

3.1 PM- Research Site: Project Start-up
   Research team responsibilities-training
   Project expectations
   Identify primary contact
   Staff coverage
   Communication procedures
   e-mail, fax, phone, correspondence
   Prepare study files
   Protocol review/adherence and compliance
   Study manual review
   CRF review
   Subject tracking and compliance
   Project timeline and test schedule review
   Sponsor monitoring plan

3.2 PM- Communications
   IRB/sponsor/CRO/FDA/subject/providers

3.3 PM- Regulatory Files
   Content of files
   Organization
   Periodic Review
   Accessibility/security
   Maintenance

3.4 PM- Hospital/Central lab Procedures
Guidelines for Writing Standard Operating Procedures (SOP)

Lab staff/project team responsibilities/communication
Expectations of standards
OSHA standards
Supply inventory
Lab Certification and normals
Equipment calibration/maintenance
Emergency procedures
Reporting

3.5 PM- Drug Accountability/Tracking/Storage
Staff responsibilities
Ordering procedure
Tracking
Dissemination/processing
Storage/special equipment (temperature logs, etc.)
DEA controlled substances
Shipping to satellite site/sponsor
Return/destuction

3.6 PM- Study Termination
Prepare for visit
Investigator obligations
Visit responsibilities
Final form audit/completion
Final drug accountability
Final document storage: FDA regulations
Study summary for IRB, sponsor
Follow-up activities
Define plan for method of document retrieval

SM: Subject Management

4.1 SM- Subject Screening
Telephone screening
Screening log/charts
4.2 SM- Subject Recruiting
Recruitment plan
PI/Sub-investigator/Ancillary staff training
Monitor enrollment goals, modify and update as needed
Accrual reporting
4.3 SM- Informed Consent Implementation
Obtaining consent
Proxy consent
Guidelines for Writing Standard Operating Procedures (SOP)

Assent of children
Minority recruitment
Copy to subject
Amendments/tracking

4.4 SM- Randomization/Coding/Blinding/Emergency Unblinding

4.5 SM- Enrollment Procedures
Protocol exemptions
Remuneration procedures

4.6 SM- Clinical Assessments
Scheduled visits
Interim visits
End-point determination

4.7 SM- Specimen Collection
Phlebotomy procedures
Processing samples
Storage and shipping

4.8 SM- Dose Modification

4.9 SM- Termination Procedures
Routine Early Withdraw
Subject Initiated
Physician Initiated

4.10 SM- Safety Reporting
FDA regulations
Staff responsibilities
Telephone reporting
Staff responsibilities
AE event determination
Written reporting procedures/format: IRB, sponsor
Source documentation, tracking and follow-up
Dissemination of report for review/final sign off: PI

DM: Data Management

5.1 DM- CRF Completion
Review for consistency/completion
CRF amendments, tracking and sign off
Use of sponsor guidelines/coding
Guidelines for Writing Standard Operating Procedures (SOP)

Investigational site procedures
On-site completion of forms
Data corrections
Remote data forms/completion/transmission to sponsor

5.2 DM- Source Documentation
Medical Records
Study Files
Laboratory Reports
Diagnostic procedure/test
Consultation notes
Medical/nursing notes

5.3 DM- Database design and management

5.4 DM- Archiving Data
Study documentation: CRF, protocol, drug accountability records, correspondence and regulatory documentation file
Tracking and updates
Procedure to retrieve data

QA: Quality Assurance (Sponsor, Investigational Site, FDA)

6.1 QA- On-Going Monitoring Visits
Pre-meeting preparation
Regulatory documentation review and update
Ongoing record keeping
Meeting responsibilities/availability of staff
Protocol violation
Monitor study team compliance
Reporting to sponsor
Follow-up activities

6.2 QA- Internal Audit
Procedures
Preparation for audit
Conducting the audit
Follow-up/closure
Final reporting

6.3 QA- Sponsor/CRO Audit
Procedures
Preparation for audit
Audit Visit
Guidelines for Writing Standard Operating Procedures (SOP)

Follow-up/closure
Final reporting

6.4 QA- FDA Inspections
Preparation
Communication to Sponsor/CRO
Conducting the visit
Follow-up, closure
Final reporting

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