

SOPs, WIs, and Forms

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Written Documents

- ◆ Standard Operating Procedures
- ◆ Work Instructions
- ◆ Workflow Forms

SOP Definition

- ✦ **Standard Operating Procedures**
 - Detailed written instructions to achieve uniformity of the performance of a specific function.

Purpose and Benefits of SOPs

- ◆ Internal training material
- ◆ Meet FDA regulations
- ◆ Opportunity to examine and improve processes
- ◆ Promote consistency and efficiency on how work is performed and checked
- ◆ Accountability

Standard Operating Procedures

- ◆ Narrow in scope
- ◆ Detailed overview
- ◆ Refers to other SOPs, Work Instructions, Workflow Forms
- ◆ Specifies who performs tasks

SOP Management

- ◆ Yearly review
- ◆ Control dates, versions
- ◆ Approvers
- ◆ Reviewers

FHI DM SOPs

- ◆ Data management plan
- ◆ Data entry system design
- ◆ Data processing and entry
- ◆ Data querying programming
- ◆ Data querying
- ◆ Medical coding
- ◆ Data set creations
- ◆ Data archiving library
- ◆ Clinical Administration
- ◆ Maintenance of regulated environment

SOPs Recommended in Recent FDA Guidance

- ◆ System setup/installation
- ◆ System operating manual
- ◆ Validation and functionality testing
- ◆ Data collection and handling (including archiving, audit trails, risk assessment)
- ◆ System maintenance
- ◆ System security
- ◆ Change control

SOPs Recommended (2)

- ◆ Data backup, recovery, and contingency plans
- ◆ Alternative recording methods
- ◆ Computer user training
- ◆ Roles and responsibilities of sponsors, clinical sites, and other parties

Sample SOP

FAMILY HEALTH INTERNATIONAL Standard Operating Procedure

| | |
|--|---|
| TITLE: Development and Review of a Data Management Plan | SOP # 601-05 |
| EFFECTIVE DATE: 01 Sept 2007 | SUPERSEDES: # 601-04 PAGE: 4 of 5 |

| Section | Description | Person(s) Responsible |
|------------|--|-----------------------|
| | <ul style="list-style-type: none"> The final version of the DM Plan must be completed and approved before any study data are received in-house. | |
| 3.2 | Send a copy of the approved DM Plan with approval signatories to the study-specific central files (See SOP 310). | DMgr or designee |
| 4.0 | <p>Changes to an approved DM Plan</p> <p>When needed, modify the DM Plan during the course of the study.</p> | DMgr |
| 4.1 | Changes in key aspects of the DM Plan (e.g., where data are collected, where data are stored, how data are entered into the system) require full approval. | DMgr |
| | NOTE: <i>Non-key changes may qualify for expedited</i> | |

Change History

- ◆ Discontinued SOPs should be archived
- ◆ Change history should be maintained on the newest SOP

History of Changes

| | | |
|------------|--|----------------------------|
| 4.2 | Restrict access to data sets according to the data freeze request form (Appendix A). | Director of RI or designee |
| 5.0 | Send an email to the DA indicating the location of the datasets. | DP |

HISTORY

| SOP # | Effective Date | Supersedes | Change |
|--------------|----------------|------------|--|
| R&D # 432 | 02/22/1993 | -- | -- |
| FHI # 607-00 | 06/01/2000 | R&D # 432 | Renumber, update |
| 607-00 | 06/01/2000 | -- | None |
| 607-01 | 15 Jan. 2005 | 607-00 | Reformatting; deletion of Scope section; annual review; clarification of procedure |
| 607-02 | 1 Mar. 2006 | 607-01 | Annual review |
| 607-03 | 1 Nov. 2007 | 607-02 | Update procedures, revision of header |

Work Instructions

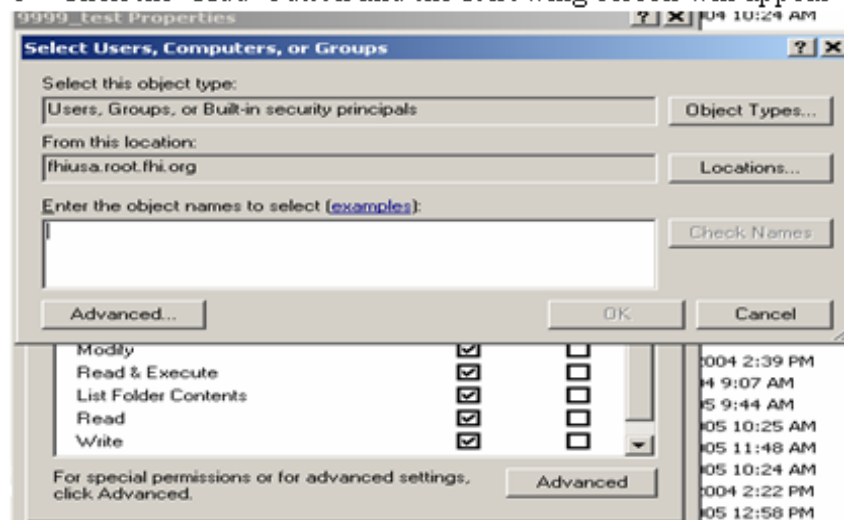
- ◆ Very detailed
- ◆ Changes frequently
- ◆ Specific to software packages

Sample Work Instruction

Work Instruction

| | | | | |
|------------------------|---|--------------------|-------------|----------------------|
| TITLE: | Generating SAS datasets from study data stored in Clintrial™ 4.x databases. | | WI # | 607-01 |
| EFFECTIVE DATE: | 11/14/05 | SUPERSEDES: | V 1.2 | PAGE: 4 of 14 |






















- Domain Admins
- ALWAYS DELETE THE FOLLOWING USERS:
 - RTP.BIOS
- Delete users who are not listed on the Freeze form as having been authorized for this study.
- To add users
 - Click the 'Add' button and the following screen will appear



Workflow Forms

- ◆ Documentation to show control over processes

FHI Workflow Forms

-  Form 602-01 Panel Type Information Form
-  Form 602-02 Study notebook memo spec testing section
-  Form 602-03 Study Notebook QA Checklist v1.4
-  Form 602-04 Study Notebook Contents v1.4
-  Form 602-05 Coding Target Table
-  Form 602-06 Study Notebook Derivations Memo
-  Form 603-01 Phase 1 validation signoff form-v1.1
-  Form 605-01 Validation Run Checklist-v1.0
-  Form 606-01 In House Coding Signoff Form-v1.2
-  Form 606-02 Coding request
-  Form 607-01 Freeze Request-v1.5
-  Form 607-02 Freeze Checklist INTERIM 4.3 Studies-v1.4
-  Form 607-03 Freeze Checklist FINAL 4.3 Studies-v 1.4
-  Form 607-04 FINAL Freeze DM Signature List-v1.3
-  Form 609-01 Request for Change to a Production Protocol-v1.9
-  Form 609-02 Checklist For Implementation to Production Instance-v1.1
-  Form 609-04 Production System Unlocking Request Form-v1.1
-  Form 609-05 Clintrial Protocol Users Access Authorization-v2.2
-  Form 609-06 Protocol Issue Report Form-v1.1
-  Form 612-02 DM Net Change Control- v1.0
-  Form 612-03 Protocol and Field Masking Request-v1.1

User Access Form

| | |
|--|---|
| Research Informatics Division Clintrial™ Protocol Users Access Authorization |  |
|--|---|

| | | | | |
|-------------------|----------------|-------------------|--|--------------|
| Section 1 | Request | | | |
| Requestor: | | Signature: | | Date: |



| | | | |
|------------------|---------------------------------|---------------------------------|---------------------------------|
| Section 2 | Account Action | | |
| Action: | <input type="checkbox"/> Create | <input type="checkbox"/> Modify | <input type="checkbox"/> Delete |

| | | | | |
|----------------------|--------------------------------|--------------------------------|---------------------------------|--|
| Section 3 | Account Information | | | |
| User Name(s): | | | | |
| User ID(s) | | | | |
| Resource: | <input type="checkbox"/> RC43T | <input type="checkbox"/> RC43P | <input type="checkbox"/> Other: | |
| Protocol ID: | | | | |

| | | | | | |
|---|-----------------------------------|--------------------------|--------------------------|--------------------------|--|
| Section 4 | Protocol Access Privileges | | | | |
| | Access Level | | | | |
| <input type="checkbox"/> Design | Full | Read | | | |
| • Database | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| • Data Entry | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| <input type="checkbox"/> Enter | Full | No Delete | Read | None | |
| • Unmerged | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| • Merged | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| • Enroll | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | |
| <input type="checkbox"/> Resolve | Full | No Delete | Read | None | |
| • Create | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

Change Control Form

Institute for Family Health
 Research Informatics Division
 Request for Change to a Production Protocol



| Section 1 | | Request details | |
|--------------------|--|-----------------|--|
| Study number: | | Study Name | |
| Requestor (Print): | | Signature: | |
| Date requested: | | Date required: | |
| Change requested: | | | |
| | | | |
| | | | |

(↓ Research Informatics Use Only ↓)

| Section 2 | | Request assessment, approval and assignment | |
|---|--|---|--|
| Designer/Programmer: | | | |
| Change Protocol: | <input type="checkbox"/> Full Protocol (See WI 609-05 section 5) <input type="checkbox"/> Customized Protocol (see attachment) <input type="checkbox"/> Request to apply changes directly to Production instance | | |
| Description of each object impacted (panels, items, codelists, page sections, etc.) Example: FU.FUVIS add option to codelist SAV_VIS 5="Unscheduled" | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Batch Flow Sheet Form

| TO BE FILLED BY SITE | | | | | | | | | | | Center # _____ | | |
|--|--|--|--|--|--|--|--|--|--|--|---------------------------|----------------------------------|--|
| 9931 NGU STUDY BATCH FLOW SHEET | | | | | | | | | | | | | |
| Date _____ Total Forms Sent _____ Total Queries Sent _____ | | | | | | | | | | | | | |
| Comments _____ | | | | | | | | | | | | | |
| PN | | | | | | | | | | | SUM | TO BE FILLED AT THE DATA CENTER | |
| EC (2) | | | | | | | | | | | | Date Received ___/___/___ | |
| BSR | | | | | | | | | | | | Total forms received _____ | |
| BQ (6) | | | | | | | | | | | | Total Queries received _____ | |
| BP | | | | | | | | | | | | Received by _____ | |
| BG | | | | | | | | | | | | | |
| FQ (5) | | | | | | | | | | | | Comments _____ | |
| FP | | | | | | | | | | | | | |
| FG | | | | | | | | | | | | | |
| TL | | | | | | | | | | | | | |
| ML | | | | | | | | | | | | | |
| FSR | | | | | | | | | | | | | |
| FCA | | | | | | | | | | | | Entry Date _____ Initials _____ | |
| SCA | | | | | | | | | | | | | |
| IV | | | | | | | | | | | | Verify Date _____ Initials _____ | |
| CM | | | | | | | | | | | | | |
| AE (2) | | | | | | | | | | | | | |
| UU | | | | | | | | | | | | | |
| DF | | | | | | | | | | | | | |
| COMPLETED POST DATA ENTRY | | | | | | | | | | | | | |
| Reconciled Date _____ | | | | | | | | | | | Reconciled Initials _____ | | |
| Comments _____ | | | | | | | | | | | | | |

SOP, WI and Forms Conclusions

- ◆ Yearly review
- ◆ Control dates, versions
- ◆ Approvers
- ◆ Reviewers

Annotate Flowchart with SOPs, Work Instructions, and Data Tracking Forms

Breakout Session

Using the flowchart you have created, add the following details:

- Where SOPs would be needed
- Where Work Instructions would be needed
- Where Forms would be needed
- Please be realistic in the amount of work you are asking the staff to perform – what is the proper balance between control and overwork?
- Please use different colors to make the flowchart more readable