


Standard Operating Procedures for Clinical Research at USF Morsani CRC			
		REGULATORY DOCUMENTATION	
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**PURPOSE:** This SOP is intended to meet Federal regulations that require documentation of all study-related activities. The regulatory files, which are periodically reviewed by the sponsor and upon request by the FDA, serve as the site's record of compliance with good clinical practice (GCP).

**SCOPE:** This SOP applies to the all clinical studies conducted at the CRC.

**RESPONSIBILITY:** The PI is responsible for maintaining all required documentation for clinical studies conducted at the CRC. The study coordinator is responsible for obtaining, maintaining and storing all required study documentation for each study.

#### DEFINITIONS:

**Confidentiality:** Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

**Direct Access:** Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.


**Documentation:** All records, in any form (including, but not limited to written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

**Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

**Inspection:** The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority (ies).

**Investigator's Brochure:** A collection of all relevant information known prior to the start-up of a clinical research study involving an investigational product (s). It includes the pre-clinical data such as chemical, pharmaceutical, toxicological, pharmacokinetic and pharmacodynamic data in animals and humans as well as the results of earlier trials.

**Note-to-File:** A description of the protocol-specific method of accomplishing a process. This document can also be used to describe the reason for a discrepancy, missing data or missing documentation and can include information regarding the location of central files.

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## DEFINITIONS (cont.):


**Quality Assurance (QA):** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

**Regulatory Binder:** Contains essential documents required to conduct a clinical study and often the first document reviewed during audits and inspections. Referred to synonymously as the Study Files, Investigator Files or Investigator Binder

**Source Documents:** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

## PROCEDURE:


1. When a study is planned, the study or regulatory coordinator will assemble a binder or electronic database to file all regulatory documentation so that it is collected properly for the study.
2. Copies of documents related to clinical studies will be kept in the regulatory binder. Copies or originals will be sent to the sponsor as appropriate.
3. Regulatory documents should be well-organized in a readily available format (ie:, reverse chronological order), preferably a ringed binder with the appropriate tabs (See Appendix I: Regulatory Binder Index and Appendix J: Regulatory Records Checklist). A Regulatory Log (Appendix K) is recommended to track most current study related documentation such as protocol amendments and changes in informed consent documents.
4. Documents may be stored in a single binder or several binders in a secure, locked area in a central location.
5. As the study progresses, the study or regulatory coordinator is responsible for the retention of documents received in the appropriate sections of the regulatory file.
6. Prior to scheduled monitor and/or auditor visits, the study or regulatory coordinator should review content of regulatory files for completeness.
7. At the end of the study, the regulatory file should be reviewed for accuracy. Missing documents should be retrieved and inserted, and discrepancies should be noted by creating a note-to-file. If the document cannot be found or replaced, a note-to- file explaining why the document is missing should be placed in the regulatory file. In the event that a document is

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**PROCEDURE (cont):**

temporarily stored outside of the regulatory binder, a note-to-file should be created indicating the document's location.

8. After the study is completed and the file is reviewed completely, the regulatory file can be stored in a safe place and made available in the event of a regulatory audit.
9. *USF HRPP Policy #906: Records Retention and Accessibility* requires the retention of regulatory files for a minimum of *five (5) years* after the study is closed by the Institutional Review Board (IRB). If the research records contain HIPAA Authorizations, including informed consent document(s) (if any), research subject requests for access or accounting of Protected Health Information (PHI) disclosures, these records must be maintained for a minimum of six years from the date of study closure or later as outlined in the HIPAA Authorization language.
10. Refer to the sponsor/funding agency's contract/agreement to determine the required regulatory document retention guidelines.
11. Document Requirements:
  - 11.1 Original or copies of the following documents must be sent to the sponsor when completed:
    - Original final signed protocol
    - Original final signed amendments
    - Final signed FDA form 1572 from each Investigator
    - Current CVs from each Investigator (and Sub-Investigators when requested)
    - Amended FDA form 1572 as available
    - Financial disclosure documentation
    - Lab certification, and normal lab values for each lab used
    - Copy of IRB approval for original protocol, advertisements, and informed consent/ HIPAA forms and all amended versions of each document
    - Copy of IRB progress reports and final report
    - Originals of all Case Report Forms (CRFs) and any other data forms including lab test data for the study
    - Original or copy of test article log for investigational test article, concomitant medications, and equipment. Copies of test article shipment and retrieval documents
    - Information of any adverse events at the CRC including IRB submissions when reported as required by IRB
    - Copies of any abstracts or manuscripts regarding the results of the study
    - Copy of IRB final report letter
  - 11.2 Study subject data requirements- Adequate and accurate record of each study subject in a clinical study should be maintained by the Investigator. These records include, but are not limited to, the following documents:
    - CRFs
    - Medical history records

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**PROCEDURE (cont):**

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- Physical exam results
- Lab test results
- Clinic notes

11.3 Investigational Test Article Record Requirements- The research nurse or Investigational Pharmacist maintains accurate and complete accounting of all clinical study materials received, disbursed, and returned to the sponsor. These records must be kept with other study records and retained as required by the sponsor and FDA.

<b>REFERENCES:</b>	FDA 21 CFR 312.60 - General responsibilities of investigators 21 CFR 312.62 - Investigator recordkeeping and record retention 21 CFR 312.68 - Inspection of investigator's records and reports 21 CFR 812.140(a) - Investigator records ICH E6: Harmonized Tripartite Guideline for GCP 2.10, 2.11 - The Principles of ICH GCP 4.9 - Records and Reports 8.0 - Essential Documents for the Conduct of a Clinical Trial USF HRPP Policy and Procedures Manual: Records Retention and Accessibility
<b>RELATED POLICIES:</b>	SOP 103: Responsibilities of the Research Team SOP 303: Site Initiation Visit SOP 310: Site Monitoring Visits SOP 311: Study Close-Out SOP 602: FDA Audits
<b>APPENDICES:</b>	Appendix I: Regulatory Binder Index Appendix J: Regulatory Records Checklist Appendix K: Regulatory Log
<b>REVISION HISTORY:</b> Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	