

## **II. RA- 200**

# **REGULATORY AFFAIRS**

- 201 Essential Documents
- 202 Initial and On-going Submissions
- 203 Reporting Requirements
- 204 Conflict of Interest

## 1. Policy

<<Site>> shall maintain a complete set of files pertaining both to specific participants (Study Files and Source Documents) and to regulatory documentation for each study conducted.

Documentation shall be maintained per SOP 105 and 201 as required by federal and local regulations, <<Site>> policies, and as stipulated in the protocol, if applicable.

Documents for each project shall be organized as follows:

- Regulatory File - This file is composed of the documents that pertain to the overall governance of the study and indicating required reviews and approvals have been obtained. They would include the protocol(s), master consent form(s), IRB approval documentation, etc.
- Study Files or Case histories - A record of all data pertinent to the conduct of the investigation. Evidence that the study has been conducted according to the requirements of the protocol and pertinent regulations are included in this file. Documents in the study files include Telephone Contact Log, logs pertaining to the investigational product receipt and accountability, eligibility logs, the investigator's "banker's box", staff signature logs, and monitoring logs.

Study file also includes the CRFs and Source Documents.

- Source Documents, are records of observations and other data pertinent to the investigation on each subject enrolled in a study. Source documents are the original records of the findings, results, and notations from visits, procedures, interviews, and tests for each subject enrolled in the study. Source documents are the basis for the data that support the findings of the research.

## 2. Scope

This SOP, in conjunction with SOP 105, addresses the fulfillment of requirements for study documentation.

## 3. Responsibility

Responsibilities for implementing this SOP are indicated as follows:

General administration: See Attachment GA 101-A: List of Key Personnel and Responsibilities at <<Site>>.

Specific studies: See Attachment GA 101-B: List of Responsibilities for <<Protocol>>

## 4. Applicable Regulations and Guidelines

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

## 5. SOP Attachments

- RA 201-A: Regulatory File Content Checklist
- RA 201-B: Study File Content Checklist
- RA 201-C: Table of ICH Essential Documents

## 6. Process Overview

- A. Maintaining Research Documents and Files
- B. Retention of Study Documents

## 7. Specific Procedures

### A. Maintaining Research Documents and Files

#	Who	Task	Attachments	Related SOPs
A-1	<<Designee>>	For each study, create a series of file folders or start a binder for documents collected during the study.  Create the files to organize and account for the regulatory documents, study documents and source documentation.	RA 201-A - C	RA 201 PM 304 SM 405
A-2		Referring to SOP 201, maintain and update the file folders or binder as necessary, adding appropriate documents as they are generated or received.  Retain copies of all original and revised documents (e.g., protocol, investigator's brochure, informed consent form).	RA 201-A - C	RA 201
A-3		When the study is over, review the contents of regulatory files and subject records for completeness by comparing with the checklists.	PM 306-A	PM 306
A-4		Ensure that files are organized and complete by following SOP GA 105 procedures to access and maintain regulatory and study files.		GA 105
A-5				
NOTE:				

### B. Retention of Study Documents

#	Who	Task	Attachments	Related SOPs
B-1	<<Designee>>	Following procedures for storage and archiving, ensure that documents are retained as required (see Note) by federal regulations (may vary according to funding source, product, and regulatory authority), local regulations (states may have certain requirements), and <<Site>> policies.	RA 201-A - C	RA 201
B-2				
B-3				
Note: Requirements for document retention varies. While documents associated with FDA-regulated studies must be retained for at least two years after the marketing application is approved for the drug/device. (If an application is not approved, until two years after the complete drug/device investigation is completed), documentation may need to be retained for up to fifteen to twenty years.				