MERCY HEALTH

Institutional Policy and Procedure
Date of Original P & P: 07/01/2009
Revision No: 2
Effective Date: 03/31/2015

Title Investigative Site – Regulatory Affairs
RA 201 Essential Documents

Originator Institutional Official

Approval 

1. Policy

Mercy Health shall maintain a complete set of files pertaining both to specific participants (Study Files and Source Documents) and to regulatory documentation, including study approvals, IRB correspondence and all general significant correspondence for each study conducted.

Documentation shall be maintained per SOP 105 and 201 as required by federal and local regulations, in alignment with ICH E6, Essential Documents, Mercy Health policies and as stipulated in the protocol, if applicable.

Essential documents include all documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

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 includes evidence of required reviews and approvals. They would include the protocol(s), any amendment(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, Delegation of Authority, evidence of staff training, qualifications and education (including CVs, Licenses and training logs), significant study-related correspondence, monitoring logs, monitoring visit follow-up letters, etc.

  Study file also includes the CRFs, Source Documents and completed/signed patient Informed Consent Forms.

  — 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 and may be paper or electronic based, or a combination of both paper and electronic medical records (EMR).

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 Mercy Health.

Specific studies: See Attachment GA 101-B: Delegation of Authority .

4. Applicable Regulations and Guidelines

FDA 21 CFR 11—Electronic Medical Records

21 CFR 50—Protection of Human Subjects

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

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7. Specific Procedures

A. Maintaining Research Documents and Files

#	Who	Task	Attachments	Related SOPs
A-1	Clinical Research Assistant/Coordinator	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 any paper-based 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. Documents should be filed in chronological order. For significant e-mail correspondence, only the latest and final chain including any final actions or decisions should be printed and retained. 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		All newsletters, Monitor Visit Follow-Up Letters and any correspondence addressed to the PI should be initialed and dated by the PI as evidence of review prior to filing the documents.		
A-4		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-5		Ensure that files are organized and complete by following SOP GA 105 procedures to access and maintain regulatory and study files.		GA 105
NOTE:				

B. Retention of Study Documents

#	Who	Task	Attachments	Related SOPs
B-1	Clinical Research Assistant/Coordinator	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), Mercy Health policies and sponsor contracts.	RA 201-A - C	RA 201
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 an extended period of time, i.e., up to 15 or 20 years.				