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 

Attachment RA 201-B

Study File Content Checklist	Version No. 01	Effective Date: 03/31/15

Study File Content Checklist		
For Protocol		
Section	**Contents**	
Study Logs and Records	☐	Subject Screening Log
	☐	Subject identification code list
	☐	Subject enrollment log
	☐	Record of retained tissue/fluid samples
	☐	Training log
	☐	Other:
Data Management	☐	Copy of Case Report Form template (paper or electronic)
	☐	Data Handling Guidelines
Subject Records	☐	Original Case Report Forms
	☐	Source documents
Source Documents*		
☐	Electronic records	
☐	Signed Consent Forms	

☐	Inpatient and outpatient medical records
☐	Progress notes
☐	Consults
☐	Nursing notes
☐	Pathology reports
☐	Radiology reports
☐	Medicine/radiation administration records
☐	Surgical reports
☐	Laboratory reports
☐	Admission forms
☐	Flow sheets that are signed and dated
☐	Protocol or study road maps
☐	Participant diaries/calendars
☐	Appointment books
☐	Deviation reports

* A source document is any document, form or record in which specific participants' data is first recorded. ICH guidelines define source documents as original documents, data and records.

FDA [21 CFR 312.62 (b)] requires that the investigator "...prepare and maintain accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation."

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