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 J Gallenis MD

Attachment RA 201-A

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

A complete Site Study File is maintained at each site and contains information relevant to it and to individual subjects. It should be organized in chronological order with the most recent entries in the front.

Regulatory File Content Checklist			
For Protocol			
Section		**Contents**	**Version Date/Comment**
Protocol and Related Reports	☐	Confidentiality Agreement	
	☐	Protocol(s) -- all versions, most recent first (attach copies of the IRB approval letters for each version)	
	☐	Amendment 1 (attach copies of the IRB approval letters for each version)	
	☐	Amendment 2 (attach copies of the IRB approval letters for each version)	
	☐	Amendment 3 (attach copies of the IRB approval letters for each version)	
	☐	Investigator Brochure or Report of Prior Investigations	
	☐	Sponsor Safety Reports (attach documentation of IRB submission)	
	☐	Decoding procedures for blinded studies	
	☐	SAE Reports: initial reports and follow up, (attach documentation of IRB submission)	

	☐	Request(s) for Waiver of Protocol (attach documentation of IRB submission) and documentation of sponsor's reply	
	☐	Report(s) of Protocol Violation(s) (attach documentation of IRB submission) and any follow up	
	☐	Annual Reports	
	☐	Final clinical study report	
	☐	FDA inspection report	
IRB* *Note: Create similar file for any other applicable regulatory authority, e.g., Radiation Safety Committee, Institutional Biosafety Committee	☐	Copy of initial IRB application (with copies of submitted material)	
	☐	Documentation of IRB approval of the study and accompanying material	
	☐	Consent form with documentation of IRB approval	
	☐	Amended consent form with documentation of IRB approval	
	☐	Amended consent form with documentation of IRB approval	
	☐	All recruitment materials with documentation of IRB approval	
	☐	Additional recruitment materials with documentation of IRB approval	
	☐	IRB approval of Amendment	
	☐	IRB approval of Amendment	
	☐	IRB approval of Amendment	
	☐	IRB approval of Amendment	
	☐	Copies of periodic reports with documentation of IRB continuing approval	
	☐	Copies of requests for protocol waiver with documentation of IRB approval	
	☐	Copies of reports of protocol deviations with documentation of submission to the IRB (i.e., IRB acknowledgement form/letter)	
	☐	Final Report	
	☐	Documentation of site-IRB communications (copies of letters, email, faxes, phone log, etc.)	
	☐	IRB member roster(s) and credentials (members at initial and each periodic review)	

Regulatory File Content Checklist		
For Protocol		
Section		**Contents**
Site Documentation	☐	1572/Investigator Agreement(s)
	☐	CVs of Investigator, sub-investigators, other key personnel
	☐	Licenses/Training Certificates

Study personnel	☐	Financial disclosure information (as required by sponsor/1572)
	☐	Personnel Delegation of Authority Log
Facilities	☐	Clinical Laboratory Certifications (CAP, CLIA) (initial and periodic)
	☐	Laboratory normal ranges
	☐	Documentation of validation/calibration for equipment used to generate data
Regulatory File	**Contents**	
Investigation-al product and study-related supplies	☐	Equipment and supplies (receipt, calibration logs)
	☐	Documentation of receipt of investigational product(s) and any control product
	☐	Documentation of dispensing of investigational product(s) and any control product
	☐	Product release forms
	☐	Shipping records, packing slips
	☐	Investigational product accountability forms
	☐	Product disposition record (return, destruction)
Data monitoring and verification	☐	Site visit/monitoring reports
	☐	Monitoring logs
	☐	Follow-up correspondence/communication documentation
	☐	Data queries
	☐	Sponsor audit documents
	☐	Study closeout information
Financial	☐	Preliminary and ongoing budget estimates
	☐	Insurance (indemnification) statement
	☐	Original signed clinical study contract
	☐	Subject compensation documentation