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-C (1 of 3 pages)

Table of ICH Essential Documents	Version No. 01	Effective Date: 03/31/15

TABLE OF ICH ESSENTIAL DOCUMENTS				
E6 Ref	**Before the trial starts**	**Sponsor**	**Site**	**IRB**
8.2.1	Investigator Brochure	•	•	•
8.2.2	Signed protocol, amendments, if any, and sample Case Report Form	•	•	•
8.2.3	Information given to trial subject -Informed Consent Form (including all applicable translations) -Other written information -Recruitment advertisements (if used)	•	•	•
8.2.4	Financial aspects of the trial	•	•	•
8.2.5	Insurance statement (where required)	•	•	
8.2.6	Signed agreement between involved parties	•	•	
8.2.7	Dated, documented approval/favorable opinion of IRB/EC of the following: -Protocol and amendments -CRF (if applicable) -Informed Consent Form(s) -Other written information to be provided to the subject(s) -Recruitment advertisement -Subject compensation (if any) -Any other documents given approval/favorable opinion	•	•	•
8.2.8	IRB/EC composition	•	•	•

8.2.9	Regulatory approval/notifications of protocol (if required)	•	•	•
8.2.10	CVs and/or other relevant documents evidencing qualifications of Investigator(s) and subinvestigator(s)	•	•	•
8.2.11	Normal value(s)/range(s) for procedure(s) and test(s) included in the protocol	•	•	
8.2.12	Medical/laboratory/technical procedures/tests -Certification -Accreditation -Established quality control and/or external quality assessment -Other validation	•		
8.2.13	Sample labeling for investigational product container(s)	•	•	
8.2.14	Instructions for handling of product(s) and other trial-related materials (if not included in protocol or IB)	•	•	
8.2.15	Shipping records for product(s) and trial-related materials	•	•	
8.2.16	Certificate(s) of analysis of product(s) shipped	•	•	
8.2.17	Decoding procedures for blinded trials	•	•	
8.2.18	Master randomization list	•		
8.2.19	Pretrial monitoring report	•		
8.2.20	Trial initiation monitoring report	•		

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TABLE OF ICH ESSENTIAL DOCUMENTS

E6 Ref	Documents required during the clinical trial	Sponsor	Site	IRB
8.3.1	Investigator Brochure updates	•	•	•
8.3.2	Any revision to: -Protocol/amendment(s) and CRF -Informed Consent Form -Any other written information provided to subjects -Advertisement for subject recruitment (if used)	•	•	•
8.3.3	Dated, documented approval of IRB/EC of the following: · Protocol amendment(s) · Revision(s) to: -Informed Consent Form -Any other written information to be provided to the subject -Advertisement for subject recruitment -Any other documents given approval/favorable opinion · Continuing review of trial	•	•	•
8.3.4	Regulatory approvals/notifications (if needed) for protocol amendment(s) and other documents	•		
8.3.5	CVs for new investigator(s) and/or sub-investigator(s)	•	•	•
8.3.6	Updates to normal value(s)/range(s) for medical/laboratory/ technical procedure(s)/test(s) included in the protocol	•	•	
8.3.7	Updates of validation/certification for facilities where protocol mandated procedures and tests are performed · Certification · Accreditation · Established quality control and/or external quality assessment · Other validation (where required)	•	•	•
8.3.8	Documentation of product and related material shipment	•	•	
8.3.9	Certificate(s) of analysis for new batches of product	•		
8.3.10	Monitoring visit reports	•		
8.3.11	Relevant communications other than site visits -Letters -Meeting notes -Notes of telephone calls	•	•	
8.3.12	Signed Informed Consent Forms		•	
8.3.13	Source documents		•	
8.3.14	Signed, dated and completed Case Report Forms (CRF)	• copy	• orig.	
8.3.15	Documentation of CRF corrections	• copy	• orig.	
8.3.16	Notification by Investigator to sponsor of serious AEs and related reports	•	•	
8.3.17	Notification by sponsor/investigator to regulatory authorities and IRB(s) of unexpected serious AEs	•	•	•

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TABLE OF ICH ESSENTIAL DOCUMENTS				
E6 Ref	**Documents required during the clinical trial**	**Sponsor**	**Site**	**IRB**
8.3.18	Notification by sponsor to Investigators of safety information	•	•	•
8.3.19	Sponsor interim/annual reports to authorities	•		
	Investigator interim/annual reports to IRB	•	•	•
8.3.20	Subject Screening Log		•	
8.3.21	Subject identification code list		•	
8.3.22	Subject Enrollment Log		•	
8.3.23	Investigational products accountability at the site	•	•	
8.3.24	Signature sheet	•	•	
8.3.25	Record of retained body fluids/ tissue samples (if any)		•	
	After Completion or Termination of the Trial			
8.4.1	Investigational product(s) accountability at site	•	•	
8.4.2	Documentation of investigational product destruction	•	•	
8.4.3	Completed subject identification code list		•	
8.4.4	Audit certificate	•	•	
8.4.5	Final trial closeout monitoring report	•	•	
8.4.6	Treatment allocation and decoding documentation		•	
8.4.7	Final report by Investigator to IRB/EC, where applicable, to the regulatory authorities		•	•
	Final report by Investigator to the regulatory authorities		•	
8.4.8	Clinical Study Report	•	•	