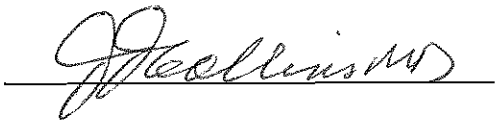
MERCY HEALTH

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

Title Investigative Site – Project Management
PM 306 Study Completion

Originator Institutional Official

Approval 

Attachment PM 306-A

End-of-Study Documentation Checklist	Version No. 01	Effective Date: 03/31/15

Resolve all outstanding data queries	☐
Resolve any outstanding EDC queries	☐
Resolve any pending monitoring findings/queries	☐
Ship all pending biological specimens to the <<designated lab>>	☐
After all protocol-specified laboratory testing is completed, archive or destroy all remaining stored specimens as specified in the Protocol (specimens obtained from participants who did not provide Informed Consent for post-study specimen storage and possible future research testing must be destroyed).	☐
In accordance with instructions provided by the Sponsor/CRO and as specified in the Protocol, return or dispose of/destroy all investigational drug/product supplies.	☐
Review and assemble for long-term storage all required essential study documents, including:	☐
Administrative and regulatory documentation	☐
Log linking participant names and ID numbers (which also serves as the completed participant identification code list required by ICH GCP guidelines)	☐
All study documents bearing participant names	☐
All study documents bearing participant identifiers	☐
All investigational product receipt, dispensing, accountability, monitoring and final disposition documentation	☐

 ISBN: 978-1-930624-67-2

Updated financial disclosure if any relevant changes occur during the course of the study or for one year following completion of the study, if applicable	☐
Final report by investigator to IRB/IEC where required, and where applicable to the regulatory authority(ies)	☐
Clinical study report	☐
To the extent possible, organize and categorize all study documentation according to ICH GCP guidelines (ICH E6, Section 8.4). Prepare a written inventory of all documentation and storage locations. Documents must be stored securely and with adequate protection of participant confidentiality for a period of [insert appropriate timeframe for IND or non-IND study].	☐
Prepare for and take part in a study close-out visit; resolve all visit findings/queries; and file all visit documentation with other study documentation.	☐
Complete, sign and date this checklist. File original with other study documentation.	☐

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