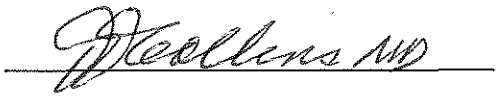
MERCY HEALTH

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	

1. Policy

Under FDA regulations, study completion occurs when all study subjects have completed the study at the investigative site. Federally funded research is considered complete after all data has been analyzed. A study may also end because the PI decides to stop participating or the sponsor terminates the study.

Clinical studies that have ended shall be closed out in an orderly and systematic manner that ensures all investigational product is accounted for and disposed of as required, specimens are stored, shipped or destroyed as required and associated source documents, study files and regulatory documentation are organized and stored in a manner that allows access by regulatory authorities and sponsor representatives for data verification and regulatory inspections.

If the trial is prematurely terminated or suspended for any reason, the <<Principal Investigator (PI) or designee >> shall promptly inform the subjects, provide follow-up for the subjects and, where required, inform the regulatory authority(ies). In addition:

- If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB/IEC and provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.
- If the sponsor terminates or suspends a trial, the investigator shall promptly inform the IRB and provide the IRB a written explanation of the termination or suspension.

  If the IRB terminates or suspends its approval, the investigator shall notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

  --IRB acknowledgement of study closure, termination or suspension shall be filed in the site regulatory file.

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2. Scope

This SOP addresses the steps that shall be taken to close clinical studies that are complete, terminated or suspended.

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 <<Protocol>>

4. Applicable Regulations and Guidelines

FDA 21 CFR 312.50—General responsibilities of sponsors

21 CFR 312.56—Review of ongoing investigations

21 CFR 312.59—Disposition of unused supply of investigational drug

21 CFR 312.60—General responsibilities of investigators

21 CFR 312.62—Investigator recordkeeping and record retention

21 CFR 312.64—Investigator reports

21 CFR 312.66—Assurance of IRB review

21 CFR 312.68—Inspection of investigator's records and reports

ICH E6: Harmonized Tripartite Guideline for GCP

4.12 Premature Termination or Suspension of a Trial

4.13 Final Report(s) by Investigator

IRB Applicable Closeout Forms and Acknowledgments

5. SOP Attachments

PM 306-A: End-of-Study Documentation Checklist

6. Process Overview

A. Completion of Study

7. Specific Procedures

A. Completion of Study

#	*Who*	*Task*	*Attachments*	*Related SOPs*
A-1	<<Clinical Research Coordinator>>	Upon verifying that a study is being closed, notify all staff involved in study activities to ensure their availability for resolving outstanding issues. If needed, meet in order to review status of the study and completion activities. If still recruiting subjects, cease recruitment activities. Cancel screening visits set up for potential subjects who have not yet been screened.	PM 306-A SM 403-B	SM 403
A-2		Contact study monitor to mutually arrange the date for the closeout visit, request a confirmation letter and a		

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		detailed list of required tasks that will occur during the closeout visit.		
A-3		Contact active subjects to schedule an early termination/completion visit. Follow protocol procedures for the early termination/completion visit.	SM 405-B, C	SM 405
A-4		Issue pro-rated outstanding payment to all subjects if applicable.		
A-5		Review source documents for completeness and follow up on receipt of results from all study-related labs, diagnostic procedures and assessments.	PM 304-A	PM 304
A-6		Complete all CRFs, EDC entry and queries issues to the extent possible. Follow up on any open AEs, SAEs and document in the subjects' study research chart.		DM 501
A-7		Document the end of study participation in the subject's research chart and remove any medication restrictions or study warnings, if applicable.		
A-8		Inventory and return all study supplies to the sponsor, if applicable. If the sponsor directs the site to dispose of or destroy remaining study supplies, request a confirmation letter with instructions/guidance.	PM 303-B, C	PM 303
A-9		Inventory investigational product, complete all applicable logs. Ensure any discrepancies are carefully documented.		
A-10		With the monitor on site, send all completed CRFs to the sponsor, if applicable. Maintain a copy of the CRFs in the subject study chart.		
A-11		Notify the IRB that the study has ended by completing and submitting the appropriate IRB documentation. Follow up with IRB for its study closure acknowledgement and file appropriately in the site regulatory binder. Forward a copy to the sponsor/CRO upon receipt.		RA 202, 203
A-12		Organize all completed CRFs and complete regulatory documentation and source documentation.	RA 201-A - C	RA 201
A-13		Follow procedures in SOP GA 105 and RA 201 to review, maintain and store study documents.		
NOTE:				