MERCY HEALTH

INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 09/02/2008
Revision No.: 4
Effective Date 12/01/2016

TITLE: Institutional Review Board Review of Research
RR 407 Study Completions

ORIGINATOR: Institutional Official

APPROVAL: _____
Institutional Official

POLICY STATEMENT: The completion or termination of the study is a change in activity and must be reported to the IRB. Although participants will no longer be "at risk" under the study, a final report/notice to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

GENERAL PROVISIONS:

1. Determining when a project can be closed:
    - HHS-supported protocols: When individually identifiable follow-up data are no longer being collected on participants enrolled in an HHS-supported protocol and analysis that could indicate new information is complete, the study may be closed.
    - Multi-site industry studies may be closed when all data analysis has been completed and the Investigator submits his or her final report.
    - Investigator initiated studies may be closed when all data analysis has been completed and the investigator submits his or her final report
2. Completion Reports

    Completion reports should be submitted within 30 days after completion or termination of the study. Completion reports may be submitted in any format that provides adequate information about the status of the study, such as computer printouts, telephone reports, letters, etc. Completion reports may be submitted by the Investigator's designee at the investigative site. The IRB Chairperson will review all reports of study completion and, if needed, request further information from the Investigator to clarify any questions that may arise.

    A listing of closed studies will be presented to the IRB at the next meeting, and copies of the Completion Report and supplementary information are made available to the IRB members upon request.

REFERENCE:
21 CFR 56.108, 56.109

45 CFR 46.103, 46.109

ATTACHMENT: RR 407-A Study Completion Form
RR 407-B Study Completion Acknowledgement

PROCEDURE: All Mercy Health Campuses

Responsibility	Action
IRB Specialist	1. Instruct Investigators to submit a Completion Report through IRBManager software system upon completion of the study. 2. Add the Study Completion Notification to the next IRB Meeting Agenda after confirming the closure submission package is complete. Obtain any outstanding information or documentation from the Investigator required to close the study. 3. Issue IRB Acknowledgement of Receipt of the Study Completion Notification after it has been reviewed by the IRB Committee or IRB Chairperson.
IRB Chairperson	1. Review the Study Completion Notification submission. Confirm package is complete and study closure is accurate and appropriate. Notify the IRB IRB Specialist that she may close out the study file permanently.

CONCURRENT CONSENTS:

Institutional Official