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

ORIGINATOR: IRB Chairperson

APPROVAL:

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:
Study closure should occur when:
• the study was not and will not be initiated;
• the study was discontinued prior to its completion;
• or the study has been completed.

Note that study closure is different from a renewal for a study that is closed to enrollment but for which data analysis continues. A study is eligible for closure if at least one of two conditions is met:
• All data analysis involving the research site(s) under the Mercy Health Regional IRB approval is complete or;
• All data has been de-identified, with no codes or keys that would allow for the potential to identify subjects in the future.

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

Version Date 12/01/2018
PROCEDURE: All Mercy Health Campuses

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<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>IRB Specialist</td>
<td>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.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1. Review the Study Completion Notification submission. Confirm package is complete and study closure is accurate and appropriate. Notify the IRB Specialist that she may close out the study file permanently.</td>
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