1.0 **Purpose:** The purpose of this standard operating practice (SOP) is to describe when and how to close a research study with the UMCIRB.

2.0 **Research Protocols Affected:**
2.1 Human research activities reviewed and approved by the UMCIRB (does not include Exempt categories of research as these have no expiration date).

3.0 **SOP:** Although a research study may be complete, the IRB must still conduct a review of what has occurred since the last time the study was approved (or renewed) and acknowledge the study will now be considered completed. Once the IRB receives and approves the application indicating completion, the researcher is no longer required to submit a continuing review for renewal. A research study may be closed when there is no further participant enrollment, research-related intervention or activities, follow-up, data collection or data analysis of identifiable data.

4.0 **Definitions:**
4.1 Closure: When all research activities have been completed and participant safety and confidentiality are no longer a concern or at risk. A study can be closed under the following conditions:
   4.1.1 No intervention or interaction is to occur with participants;
   4.1.2 No identifying information is attached to data collected from or about an individual;
   4.1.3 If funded, the sponsor has agreed that the IRB approval is no longer needed; and
   4.1.4 If funded, expenditures for the study have been completed and the account is to be closed.

5.0 **Responsibilities:**
5.1 **Principal Investigator (PI) will**
   5.1.1 Ensure research studies eligible to be closed are closed prior to the study’s IRB expiration date.
   5.1.1.1 If the study is funded or sponsored by an outside agency, the PI should verify that the study can be closed locally.
   5.1.2 Complete and submit the electronic application to close the study before the study approval expires.
   5.1.3 Maintain the IRB letter acknowledging the study has been closed.
5.2 **Office of Research Integrity and Compliance (ORIC) will**
   5.2.1 Provide assistance and guidance in training research team members and IRB members in the proper method of conducting continuing review.
   5.2.2 Pre-review closure information for completeness prior to IRB review.
   5.2.3 Process letter to acknowledge closure and send to study team.
   5.2.4 Report closures to UMCIRB members and other appropriate officials within the UMCIRB minutes.
5.3 **UMCIRB Chairperson or designee will**
   5.3.1 Review final information for research studies submitted for closure and request any
information that may be needed to confirm research activities since the last review of the research.

5.3.1.1 Closures can be reviewed and approved utilizing expedited review (i.e., review by the Chairperson or designee), however the study team will be notified if review by the Convened UMCIRB is required.

6.0 Procedures:
6.1 Investigator ensures that the study is eligible to be closed.
6.2 Investigator/study team member completes and submits the same electronic IRB application required for Continuing Review but indicates they are now closing the study and this is the final report.
6.3 A researcher may not collect data or perform any protocol required activities under a research study that has been closed; the researcher would need to re-open the study as a brand new study in order to conduct any further human research. Additional research projects using data acquired in the approved study may constitute new human research subject to separate IRB review.

Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<tr>
<td>4.25.2016</td>
<td>1.0</td>
<td>Pulled information to a stand-alone document.</td>
<td>All</td>
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References:
FDA. Code of Federal Regulations:

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109