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).

3.0 **SOP:** Once a research study is complete, the IRB will conduct a review of what has occurred since the last time the study was approved (or renewed) and acknowledge the study will be considered completed in the IRB records. The IRB will receive and approve the application via a Final Report within the electronic submission system.

4.0 **Definitions:**
4.1 **Final Report** is the activity within the electronic IRB Submission system that creates an application to close the specified study. This application is generated, completed and Submitted by the PI (or other study team members) and reviewed by the IRB.

4.2 **Closure** is the act of submitting a Final Report to the IRB to indicate a study is complete. A study can be closed under the following conditions:

4.2.1 Non-FDA regulated human research that was approved on or after the effective date (1/21/2019) for the revised human research regulations (or amended to comply with these new revised regulations) may be closed with the IRB when the research is permanently closed to the enrollment of new subjects and the research is:

- 4.2.1.1 At the point where data analysis (of identifiable or de-identified data) only is occurring,
- 4.2.1.2 Only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, or
- 4.2.1.3 Completed.

4.2.2 Non-FDA regulated human research that was approved prior to the effective date (1/21/2019) for the revised human research regulations (and not amended to comply with these new revised regulations) may be closed with the IRB when the research is permanently closed to the enrollment of new subjects and the research is:

- 4.2.2.1 At the point where data analysis of de-identified data only is occurring, or
- 4.2.2.2 Completed.

4.2.3 FDA regulated human research may be closed with the IRB when it is closed to enrollment of new subjects and:

- 4.2.3.1 There are no further research-related intervention or activities,
- 4.2.3.2 There is no further follow-up required,
- 4.2.3.3 There is no further data collection or data analysis of identifiable data planned, and
- 4.2.3.4 The sponsor/funding agency has verified the study can be closed.

5.0 **Responsibilities:**
5.1 **Principal Investigator (PI) will**
5.1 Ensure research studies eligible to be closed are closed prior to the study’s IRB expiration date or prior to the Expected End Date (for non-FDA regulated expedited studies).

5.1.1 If the study is funded or sponsored by an outside agency, the PI should verify with the agency that the study can be closed locally.

5.1.2 If funded, expenditures for the study should be completed and the account is to be closed.

5.1.3 If an expedited study (with no expiration date) is not yet done by the time of the Expected End Date (provided by the PI in the original IRB application), an Amendment must be submitted to modify that date.

5.1.4 Complete and submit the Final Report application within the electronic IRB system.

5.1.5 Maintain the IRB letter acknowledging the study has been closed.

5.2 UMCIRB Office staff will

5.2.1 Provide assistance and guidance in training research team members about when it is appropriate and how to submit Final Reports, and IRB members in the proper method of conducting reviews of Final Reports.

5.2.2 Pre-review Final Reports for completeness prior to IRB review.

5.2.3 Process letter to acknowledge closure and send to study team.

5.2.4 Report study closures to UMCIRB members and other appropriate officials within the UMCIRB minutes.

5.2.5 Retain study records in an accessible manner for the appropriate amount of time prior to destruction.

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 Final Reports 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 a Final Report within the electronic IRB submission system.

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 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>Change</th>
<th>Reference Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.25.2016</td>
<td>Pulled information to a stand-alone document.</td>
<td>All</td>
</tr>
<tr>
<td>1.21.2019</td>
<td>Updated to reflect revised regulations surrounding continuing review and subsequent process changes.</td>
<td>Sections 2.0-6.0</td>
</tr>
</tbody>
</table>
References:

FDA. Code of Federal Regulations:

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