 Avera Institutional Review Board	Standard Operating Procedure Number: 405	Title: Closing a Research Study
	Version: 3.0	Effective Date: 3/12/2021

1. PURPOSE

This procedure describes when a research study may be closed by the IRB.

2. PROCEDURE

The completion or termination of a research study is a change in activity and must be reported to the IRB. A final report is submitted by the Investigator to notify the IRB of the completion or termination of a research study, including studies determined to be exempt. A final report provides information to the IRB regarding the final status of the research study and allows the IRB to close the study file. In the event that the Investigator fails to apply for continuing review or fails to submit a final report, the IRB will administratively close the study. When final reports are acknowledged by the IRB, the study file is closed and no further activity related to the study may be conducted.

3. SPECIFIC PROCEDURES

3.1 When to close a Research Study with the IRB

Research studies no longer needs IRB oversight when all of the following criteria are reached:

- a) The research is permanently closed to the enrollment of new subjects by the Principal Investigator (PI);
- b) All subjects enrolled by the PI have completed all research-related interventions and follow-up;
- c) there are no planned long-term follow-up data gathering activities on subjects enrolled by the PI; and
- d) Analysis of identifiable data is no longer being performed (or, as may be the case in a sponsored multicenter study, the PI is not conducting the data analysis).


If applicable, the final report the sponsor or sponsor representative has indicated the study is closed at the local site and all data analysis at the local site is completed.

3.2 Final Reports

- a) Once all activities are complete and there is no longer a need to access identifiable participant information, the study should be closed out with the IRB. PIs are encouraged to notify the IRB by submitting study closure within 30 days after completion or termination of the study. The PI's designee may submit the reports.
- b) The following should be submitted to the IRB to close the study:
 - o Final report/Closure Report (initiated within the electronic IRB system).
 - o Preliminary or final results, if available.
 - o Sponsor documentation of study completion or termination, if available.
- c) The IRB Staff will review all reports of study completion and, if needed, request further information from the PI or his/her designee. Once the IRB has determined that sufficient information has been provided, the PI will receive acknowledgement of the final report and closure of the study.
- d) A listing of closed studies will be presented to the IRB as per the standard process.

3.3 Research Study Closure When IRB Approval Has Expired

PI should submit a study closure to the IRB even if the IRB approval of the study has expired.

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3.4 Administrative Closure of a Research Study

If a study is expired and an application for continuing review or a final report has not been submitted, the study may be administratively closed by the IRB.

4. RESPONSIBILITY

The IRB Staff are responsible for ensuring that all study completion documentation is reviewed and filed appropriately.

IRB Staff are responsible for administratively closing a research study that has expired.

PI or PI's designee is responsible for submitting study closure documents.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109

45 CFR 46.103, 46.109

6. REFERENCED DOCUMENTS

Final Report

Study Closure

Revision Number	Version Date	Approved By	Date Approved
3.0	2/18/2021	Avera Institutional Official	3/12/2021
<ul style="list-style-type: none"> Clarified when a study can be closed down by the IRB. Revised wording for clarity. If a study is expired and an application for continuing review or closure has not been submitted, the study may be administratively closed by the IRB. 			
2.0	7/03/2019	Avera Institutional Official	8/8/2019
<ul style="list-style-type: none"> IRB will send the PI a study closure letter if it becomes aware that the study expired. If the IRB isn't able to contact a PI after several attempts, the IRB staff will administratively close the study. 			
1.0	August 2016	Director HSRP / August 2016	