UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-026
AAHRPP:	Element II.2.H. & Element II.5.A
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Reviewed By:	IRB Chairs; IRBs; ORIO
Procedure Title:	Study Closure

1.0 Objective

1.1. To describe the policies and procedures for closing studies at the University of Southern Maine. Studies include Institutional Review Board (IRB) approved research protocols and Human Research Protection Program (HRPP) reviewed projects and research protocols (Not Research, Not Human Subjects Research, Not Engaged, Student Classroom Project, and Exempt determinations).

2.0 General Description

2.1. The Principal Investigator (PI), Office of Research Integrity and Outreach (ORIO), or the IRB may close studies under certain circumstances.

2.1.1. The status of study activities dictates the process by which closure is completed.

2.2. The PI is responsible for promptly closing out a study if any of the following conditions exist:

2.2.1. All research/clinical investigation activities including data analysis and reporting are complete;

2.2.2. The PI never initiated the study;

2.2.3. Accrual for the study is finished, all data collection is complete, and the only remaining activity is analysis of de-identified data; or

2.2.4. The PI plans to leave the University and intends to continue the study at another institution.

2.2.4.1. The study should not be closed at University of Southern Maine (USM) until there is an active IRB approved protocol at the institution to which the PI is transferring. (*See HRPP 005 Departing Principal Investigation*).

2.3. The IRB may suspend or terminate IRB approval. (See HRPP 041 Termination or Suspension of Research SOP).

3.0 Definitions

3.1. **Administrative Closure** means a Study Closure has been executed by ORIO Staff as an administrative function because:

3.1.1. A lapse of approval resulted due to non-response to requests for Continuing Review or Final Report;

3.1.2. A period of three (3) years has passed from the original submission date of HRPP reviewed projects granted Not Research, Not Human Subjects Research, Not Engaged, or Student Classroom Project determinations; or

3.1.3. A period of three (3) years has passed from the submission date of the last amendment (or original submission if no amendment was filed) of HRPP reviewed research protocols granted an Exempt determination.

3.2. **Final Review** means a Study Closure has been executed by the IRB or IRB Designee because:

3.2.1. The PI submits a Final Report to the IRB; and

3.2.1.1. The researcher did not initiate any research activities (e.g., did not collect data from records; did not enroll subjects; did not receive samples); or

3.2.1.2. All of the following conditions are met:

3.2.1.2.1. Interaction or intervention with currently enrolled subjects is complete;

3.2.1.2.2. Data is no longer being collected from currently enrolled subjects and/or samples;

3.2.1.2.3. Long-term follow-up is complete; and

3.2.1.2.4. Analysis of identifiable data is complete.

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this Standard Operating Procedure (SOP).

5.0 Procedure

5.1. Final Review of Research Protocols

5.1.1. If a study, previously granted IRB approval or Exempt determination, qualifies for closure, the PI submits a Final Report through the online IRB submission process.

5.1.2. ORIO staff screen the Final Report for accuracy and completeness.

5.1.3. The RCA assigns an IRB member to conduct a review of the Final Report.

5.1.3.1. Regardless of initial protocol process type (exempt, full, or expedited review), protocols undergo expedited review procedures for Final Review unless the IRB member reviewing the submission determines the circumstances surrounding the request for closure require full review.

5.1.4. Final Review (FR) outcomes may include:

5.1.4.1. Request for revisions and/or additional information;
5.1.4.2. Full review at a convened meeting;
5.1.4.3. Request that the PI attend the convened IRB meeting at which the FR is scheduled for full review;
5.1.4.4. Study Closure; or
5.1.4.5. Denial of the FR and requirement of a Continuing Review submission.

5.1.5. Once the Final Review is complete: Study Closure is documented, the protocol status is set to inactive, approval is terminated, and the PI is notified of the outcome.

5.2. Administrative Closure of IRB Approved Research Protocols

5.2.1. Approximately three (3) months prior to the IRB approval end date, the PI is prompted by email to initiate either a request for Continuing Review or a Final Report.

5.2.2. If the PI fails to submit a Continuing Review or Final Report, or fails to submit requested information related to one of those, ORIO staff will execute an Administrative Closure.

5.2.2.1. If research continues past the IRB approval end date without submission of a Continuing Review or Final Report, a non-compliance investigation will ensue. (See HRPP 004 Noncompliance).

5.2.3. On the IRB approval end date: Administrative Closure is documented, the protocol status is set to inactive, approval is terminated, and the PI is notified of the outcome.

5.3. Administrative Closure of HRPP Approved Research Protocols

5.3.1. A PI will not be prompted by email to initiate a Final Report for a research protocol granted an Exempt determination.

5.3.2. On the date that three (3) years has passed from the submission date of the last amendment (or original submission if no amendment was filed): Administrative Closure is documented, the protocol status is set to inactive, and the PI is notified of the outcome.

5.4. Administrative Closure of HRPP Reviewed Projects

5.4.1. A PI will not be prompted by email to initiate a Final Report for a project granted a Not Research, Not Human Subjects Research, Not Engaged, or Student Classroom Project determination.

5.4.2. On the date that three (3) years has passed from the original submission date of the project: Administrative Closure is documented, the protocol status is set to inactive, and the PI is notified of the outcome.

5.5. Reactivating Projects and Research Protocols

5.6. Document Retention and Destruction

5.6.1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least three (3) years (or six (6) years if PHI is involved) after Study Closure, taking measures to prevent accidental or premature destruction of these documents.

5.6.2. For research under the authority of FDA or other regulatory agency, the PI retains signed documents and IRB records for the period specified in the applicable regulations if the requirements are longer than three (3) years (or six (6) years if PHI is involved) after Study Closure.

5.6.3. For multi-site studies, the PI consults the study sponsor regarding retention requirements but must maintain records for a minimum of three (3) years (or six (6) years if PHI is involved). A PI may re-initiate research inactivated by the IRB by submitting a new IRB application for the project.

5.5.2. The research in such cases is treated like a new initial review submission and managed accordingly.

5.6.4. Investigators store records consistent with the plan approved by the IRB in a secured manner to prevent breaches of confidentiality.

5.6.5. Investigators store records in compliance with any applicable state laws, federal laws, contractual agreements, or institutional policies.

5.6.6. The PI ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.

6.0 References

6.1. The University of Southern Maine Policies, Procedures and Guidance for Human Subjects Research