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:	Protocol Closure

1.0 Objective

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

2.0 Responsibility

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

2.2. It is the responsibility of the Principal Investigator (PI) to keep IRB approval end dates and admin check-in dates and submit a Renewal or Closure before said date.

3.0 General Description

3.1. The PI, ORIO or the IRB may close protocols under certain circumstances.

3.1.1. The status of protocol activities dictates the process by which closure is completed.

3.2. The PI is responsible for promptly closing out a protocol if any of the following conditions are met:

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

3.2.2. The PI never initiated the protocol;

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

3.2.4. The PI plans to continue the protocol at another institution.

3.2.4.1. The protocol should not be closed at USM until there is an active protocol at the institution to which the PI transfers. (*See HRPP 005 Departing Principal Investigation*).

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

4.0 Definitions

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

4.1.1. A lapse of IRB approval resulted or due to non-response to requests for Renewal or Closure submissions;

4.1.2. A Renewal or Closure submission was not submitted before an admin check-in date or a period of no more than three (3) years has passed from the Initial or latest Renewal determination date of research protocols granted an Exempt determination.

4.1.3. A Renewal or Closure submission was not submitted prior to an admin check-in date or a period of no more than two (2) years has passed from the Initial or latest Renewal determination date of projects granted Not Research, Not Human Subjects Research, Not Engaged, or Student Classroom Project determinations.

4.2. Final Review means a Closure has been reviewed and approved by the IRB, an IRB Member, or ORIO Staff because:

4.2.1. The PI submits a Closure, and it is confirmed that:

4.2.1.1. 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

4.2.1.2. All of the following conditions are met:
- 4.2.1.2.1. Interaction or intervention with currently enrolled subjects is complete;
- 4.2.1.2.2. Data is no longer being collected from currently enrolled subjects and/or samples;
- 4.2.1.2.3. Long-term follow-up is complete; and
- 4.2.1.2.4. Analysis of identifiable data is complete.

5.0 Procedure

5.1. Final Review of Research Protocols

5.1.1. If a protocol previously granted IRB approval or ORIO determination qualifies for closure, the PI submits a Closure through the IRB submission platform.

5.1.2. ORIO staff screen the Closure for accuracy and completeness.

5.1.3. The RCA assigns an IRB member or ORIO staff to conduct an FR of the Closure.

5.1.4. 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. Protocol Closure; or
5.1.4.5. Denial of the FR and requirement of a Renewal submission.

5.1.5. Once the FR is complete, the protocol closure is documented, the protocol status is set to inactive, approval is terminated, and, if feasible, the PI may be 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, if feasible, the PI may be prompted to initiate either a request for Renewal or a Closure.

5.2.1.1 It is the responsibility of the PI to keep IRB approval end dates and submit a Renewal or Closure before said date.

5.2.2. If the PI fails to submit a Renewal or Closure 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 Renewal or Closure, a non-compliance investigation may ensue. (*See HRPP 004 Noncompliance*).

5.2.2.2. After the IRB approval end date: Administrative Closure is documented, the protocol status is set to inactive, approval is terminated, and, if feasible, the PI is notified of the outcome.

5.3. Administrative Closure of Exempted Research Protocols

5.3.1. Approximately three (3) months prior to the administrative check-in date, if feasible, the PI may be prompted to initiate either a request for Renewal or a Closure for a research protocol granted an Exempt determination.

5.3.1.1. It is the responsibility of the PI to keep administrative check-in dates and submit a Renewal or Closure before said date.

5.3.2. If the PI fails to submit a Renewal or Closure or fails to submit requested information related to one of those, ORIO staff will execute an Administrative Closure.

5.3.2.1. If research continues past the administrative check-in date without submission of a Renewal or Closure, a non-compliance investigation may ensue. (*See HRPP 004 Noncompliance*).

5.3.2.2. After the administrative check-in date: Administrative Closure is documented, the protocol status is set to inactive, approval is terminated, and, if feasible, the PI may be notified of the outcome.

5.4. Administrative Closure of HRPP Reviewed Protocols

5.4.1. Approximately three (3) months prior to the administrative check-in date, if feasible, the PI may be prompted to initiate either a request for Renewal or a Closure for a project granted a Not Research, Not Human Subjects Research, Not Engaged, or Student Classroom Project determination.

5.4.1.1. It is the responsibility of the PI to keep administrative check-in dates and submit a Renewal or Closure before said date.

5.4.2. If the PI fails to submit a Renewal or Closure or fails to submit requested information related to one of those, ORIO staff will execute an Administrative Closure.

5.4.2.1. If work on the project continues past the administrative check-in date without submission of a Renewal or Closure, a non-compliance investigation may ensue. (*See HRPP 004 Noncompliance*).

5.4.2.2. After the administrative check-in date: Administrative Closure is documented, the protocol status is set to inactive, approval is terminated, and, if feasible, the PI may be notified of the outcome.

5.5. Document Retention and Destruction

5.5.1. 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

protocol closure, taking measures to prevent accidental or premature destruction of these documents.

5.5.2. For research under the authority of the 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 protocol closure.

5.5.3. For multi-site research, the PI consults the protocol sponsor regarding retention requirements but must maintain records for a minimum of three (3) years or six (6) years if PHI is involved.

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

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

5.5.6. 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. HHS, "Guidance on IRB Continuing Review of Research," November 10, 2010

6.2. FDA, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval," February 2012