

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-005
AAHRPP:	Element III.2.B.
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Reviewed By:	ORIO; Institutional Review Board
Procedure Title:	Departing Principal Investigators

1.0 Objective

- 1.1** To describe the process for departing Principal Investigators (PI) of human subject research protocol(s) to fulfill their responsibilities to either arrange for the transfer of active protocol(s) to another University investigator, to close the protocol(s) at the University of Southern Maine (USM), or to arrange for review and approval of the active protocol(s) at their new institution.

2.0 General Policy

- 2.1.** PIs who are departing USM are responsible for ensuring that human subject research-related duties are transitioned or completed before officially exiting their positions. Failure to do so may adversely affect research participants and may result in study suspension or closure by the Institutional Review Board (IRB).

3.0 Definitions

- 3.1. Principal Investigator:** Any USM faculty, staff member, student, or individual so designated in an application for external review who is the primary person responsible for all aspects of the research project and assumes all responsibilities for the results. This definition includes faculty advisors of student-conducted research.
- 3.2. Departing:** A PI is classified as departing from USM when the PI: (1) vacates their position at USM; (2) fulfills the terms of their employment. Departing from USM is not limited to the former classifications. Departure from USM includes, but is not limited to, termination, resignation, layoff, and retirement. Departure may also apply by virtue of other applicable laws, rules, bylaws, and regulations adopted by USM.

4.0 Responsibility

- 4.1.** Execution of SOP: Office of Research Integrity and Outreach (ORIO) Staff, Research Integrity Officer (RIO), Research Compliance Administrator (RCA), Principal Investigator (PI).

5.0 Procedure

5.1. Designation of New Principle Investigator

- 5.1.1. The study (or studies) may continue at USM with an amendment to the protocol(s) initiating the proper transfer of duties to a newly designated Principal Investigator. Under these circumstances, PIs should identify a qualified successor and facilitate the transfer of their responsibilities.
- 5.1.2. Depending on the IRB submission process that was originally followed, this can be accomplished in the following ways:
 - 5.1.2.1. Originally submitted as electronic: The departing PI may submit an Amendment to the protocol(s) identifying the successor PI.
 - 5.1.2.2. Originally submitted as paper: The departing PI may submit a Protocol Revision and Amendments Form for the protocol(s) identifying the successor PI.

5.2. Close the Protocol(s)

- 5.2.1. Provided that all study-related interventions with participants and data analysis have ended, the study (or studies) may be closed by the PI prior to their departure from USM.
- 5.2.2. Depending on the IRB submission process that was originally followed, this can be accomplished in the following ways:
 - 5.2.2.1. Originally submitted as electronic: The departing PI may submit a Final Report for the protocol(s), noting the completion.
 - 5.2.2.2. Originally submitted as paper: The departing PI may submit a Request for Continuing Review/Study Completion Form for the protocol(s), noting the completion.

5.3. Transfer research protocol(s) to the destined institution

- 5.3.1. The study (or studies) may continue at the destined institution. The departing PI is responsible for obtaining approval from the destined institution's IRB and closing the protocol(s) at USM prior to his or her departure from USM.
- 5.3.2. Depending on the IRB submission process that was originally followed, the closing of the protocol(s) can be accomplished in the following ways:
 - 5.3.2.1. Originally submitted as electronic: The departing PI may submit a Final Report for the protocol(s), noting the completion. The departing PI will then obtain appropriate approval from the destined institution.

5.3.2.2. Originally submitted as paper: The departing PI may submit a Request for Continuing Review/Study Completion Form for the protocol(s), noting the completion. The departing PI will then obtain appropriate approval from their destined institution.

5.4. Remain on research protocol(s) with IRB approval from the destined institution

5.4.1. The study (or studies) may continue at USM under the oversight of an appropriate, newly-designated PI at USM, and the departing PI may remain on the protocol(s) in a different capacity (typically as a co-PI) with documentation of approval from his or her new institution's IRB.

5.4.2. Depending on the IRB submission process that was originally followed, this can be accomplished in the following ways:

5.4.2.1. Originally submitted as electronic: The departing PI may submit an Amendment to the protocol(s) identifying their new role in the study, identifying the successor PI, and attaching appropriate documentation from the destined institution.

5.4.2.2. Originally submitted as paper: The departing PI may submit a Protocol Revision and Amendments Form for the protocol(s) identifying their new role in the study, identifying the successor PI, and attaching appropriate documentation from the destined institution.

6.0 References

6.1. 45 CFR 46