UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-035
AAHRPP:	Element I.1.D, Element III.1.D., Element III.2.B, & Element III.2.C.
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Prepared By:	Casey Webster, Research Compliance Administrator
Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Roles and Responsibilities of Investigators

1.0 Objective

1.1. To describe the roles and responsibilities of investigators at the University of Southern Maine.

2.0 Responsibility

2.1. 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).

2.2. The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable USM policies and procedures and federal, state, and local laws and regulations.

2.3. The PI is responsible for the oversight of the research and informed consent process.

2.4. The faculty or staff advisor (Advisor) holds the same responsibilities as a PI.

3.0 General Description

3.1. A PI must meet the definition of investigator in *HRPP-008 Determination of Activities Requiring IRB Review*.

3.2. A PI must be operating within their role at USM to oversee the conduct of the research.

3.3. A PI may delegate tasks to members of the research team but the PI retains the ultimate responsibility for the conduct of the study.

3.4. A PI leaving USM is responsible for notifying the ORIO of their departure in accordance with *HRPP-005 Departing Principal Investigator*.

3.5. The following individuals may serve as PI for research:

3.5.1. Faculty;

3.5.2. Staff; and

3.5.3. Students with an Advisor.

4.0 Responsibilities

4.1. Principal Investigators

4.1.1. As a general condition for the approval of a research study, the IRB holds the PI of the study responsible for ensuring that:

4.1.1.1. Risks to research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

4.1.1.2. Risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result;

4.1.1.3. Selection of human subjects for research participation is equitable;

4.1.1.4. Individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human research subject, or their legally authorized representative, in accordance with, and to the extent required, by USM policies and federal regulations;

4.1.1.5. Informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by USM policies and federal regulations;

4.1.1.6. Where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects;

4.1.1.7. The privacy of human research subjects is protected and the confidentiality of data is maintained; and

4.1.1.8. Appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).

4.1.2. As a specific condition for the approval of a research study, the IRB holds the PI of the study responsible for:

4.1.2.1. Promptly responding to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB renewal;
4.1.2.2. Ensuring that adequate resources and facilities are available to carry out the proposed research study;
4.1.2.3. Abstaining from enrolling any individual in a research study:

4.1.2.3.1. Until such study is approved in writing, by the IRB;
4.1.2.3.2. During any period when the IRB or sponsor has suspended study activities; or
4.1.2.3.3. Following IRB or sponsor-directed termination of the study;

4.1.2.4. Ensuring that all other investigators (research staff, students, associates, colleagues, etc.) and other personnel assisting in the conduct of the research study are appropriately informed of:

4.1.2.4.1. The study procedures;
4.1.2.4.2. Informed consent requirements;
4.1.2.4.3. The potential adverse events associated with study participation and the steps to be taken to reduce potential risks;
4.1.2.4.4. Reportable new information requirements; and
4.1.2.4.5. Data collection and record-keeping criteria;

4.1.2.5. Conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject;
4.1.2.6. Reporting of deviations from the currently approved research protocol;
4.1.2.7. Requesting IRB approval of any proposed modification to the research protocol or informed consent documents prior to implementing such modifications;
4.1.2.8. Obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent documents (i.e., unless the IRB has granted a waiver of the consent process);
4.1.2.9. Maintaining adequate, current, and accurate records of research data, outcomes, and reportable new information to permit an ongoing assessment of the risk/benefit ratio of study participation;
4.1.2.10. Reporting promptly to the IRB (and, if applicable, the sponsor and Food and Drug Administration (FDA)) any internal or external adverse event that is considered to be unexpected, serious, and possibly or definitely related to the study;
4.1.2.11. Reporting promptly to the IRB any significant changes in the risk/benefit of study participation;
4.1.2.12. Ensuring that, in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible;

4.1.2.13. Ensuring that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study;
4.1.2.14. Ensuring that all investigators have the appropriate credentials to conduct the portion of the study in which they are involved and have completed the applicable USM required training;
4.1.2.15. Maintaining adequate and accurate research subject records to reflect adherence to protocol specific requirements; and
4.1.2.16. Complying with any additional requirements as applicable.

4.2. Other Investigators

4.2.1. Appropriately qualified investigators may perform tasks as delegated by the PI but they may not accept primary responsibility for the research study.

4.2.2. As a specific condition for the approval of a research study, the IRB holds the PI of the study responsible for:

4.2.2.1. Maintaining appropriate credentials to conduct the portion of the study in which they are involved;
4.2.2.2. Completing the applicable USM-required and any protocol-specific training;
4.2.2.3. Adhering to the USM policies and procedures and federal, state, and local laws and regulations regarding the safety and protection of human participants; and
4.2.2.4. Assuring that participant privacy is protected and the confidentiality of data is maintained.

4.3. Advisors

4.3.1. Advisors must take an active role in student research activities and provide supervision for the entire duration of the study.

4.3.2. As a specific condition for the approval of a research study, the IRB holds the Advisor of the study responsible for:

4.3.2.1. Contacting the ORIO to discuss policies and procedures for obtaining IRB review before the initiation of student research activities.
4.3.2.2. Being familiar with USM policies and federal regulations regarding the conduct of human subjects research;
4.3.2.3. Being able to navigate the ORIO website;
4.3.2.4. Completing the applicable USM required training;
4.3.2.5. Understanding which review process is applicable to the student study (Determination of Research Involving Human Subjects, Undergraduate Social Work Determination, etc.)
4.3.2.6. Assisting students with submission to the ORIO or IRB.

4.3.2.7. Assisting students with the drafting of all research related materials and reviewing said materials;
4.3.2.8. Reviewing the scientific integrity, rigor, and merit of proposed student research;
4.3.2.9. Educating students on the role of the ORIO and IRB along with the importance of a HRPP;
4.3.2.10. Ensure student completion of applicable USM required training;
4.3.2.11. Maintaining ethical standards and ensuring student research is conducted to the highest ethical standards;
4.3.2.12. Educating students on the implementation of ethical standards in the conduct of their research;
4.3.2.13. Assisting students in their responses to any questions or comments from the ORIO or IRB;
4.3.2.14. Reporting of deviations from the currently approved research study, adverse events, or other research-related problems;
4.3.2.15. Ensuring requests for IRB approval are submitted by students for any proposed modification to the research protocol or informed consent documents prior to implementing such modifications;
4.3.2.16. Requiring timely submission of the research study for IRB renewal if applicable;
4.3.2.17. Requiring timely submission of a Final Report upon completion or termination of the student research; and
4.3.2.18. All additional and applicable general and specific responsibilities of a PI.

5.0 References

5.1. 21 CFR 312.50;

5.2. 21 CFR 812.100;

5.3. 21 CFR 812.110;

5.4. FDA Information Sheet: Frequently Asked Questions – Statement of Investigator (Form FDA 1572);

5.5. OHRP Frequently Asked Questions: Investigator Responsibilities FAQs