UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-012
AAHRPP:	Element I.1.A., Element I.1.B., Element I.1.C., & Standard I-2
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Prepared By:	Casey Webster, Research Compliance Administrator
Reviewed By:	IRB Chair; IRB; ORIO
Updated By:	Tina Aubut
Procedure Title:	Authority of the Human Research Protection Program

1.0 Objective

1.1. To describe the authority and delegation of responsibility of the Human Research Protection Program (HRPP) at the University of Southern Maine (USM).

2.0 General Description

2.1. The HRPP is designed to comply with Federal Regulations, state, and local laws to protect individuals from harm, provide an equitable selection of subjects, and maximize the benefits and minimize the risks of research participation.

2.2. The HRPP requires the application of all U.S. Department of Health and Human Services (DHHS) Common Rule and U.S. Food and Drug Administration (FDA) requirements to all human subject research regardless of funding or governing Federal Agency.

2.2.1. USM has chosen to limit the scope of its Federalwide Assurance (FWA) to federally-funded human subjects research only.

2.3. Differences in policy from the Common Rule requirements will be described when appropriate.

3.0 Definitions

3.1. **Engaged** means an institution's employees or agents obtain, for the purposes of the research project:

3.1.1. Data about the subjects of the research through intervention or interaction with them;

3.1.2. Identifiable biospecimens or identifiable private information about the subjects of the research; or

3.1.3. The informed consent of human subjects for the research.

3.2. Employee or agents means individuals who:

3.2.1. Act on behalf of the institution;

3.2.2. Exercise institutional authority or responsibility; or

3.2.3. Perform institutionally designated activities.

3.2.3.1. Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

3.3. Federalwide Assurance (FWA) means a legally-binding agreement administered by the DHHS Office of Human Research Protections (OHRP).

3.3.1. The FWA governs all human subjects research receiving, or eligible to receive, federal funds.

3.3.2. In addition, a number of Federal Agencies have adopted the requirements of the DHHS Common Rule and as such, any research that complies with the FWA will also meet their requirements.

3.4. Institutional Official (IO) means the highest institutional official who has the legal authority to represent USM's FWA.

4.0 Responsibility

4.1. USM and its faculty, staff, and students share in the collective responsibility for the protection of human research participants and, more broadly, for the ethical conduct of research.

4.2. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), and Institutional Official (IO) to execute this SOP.

4.3. The IO is responsible for the HRPP at USM and has the authority to implement the program.

4.4. The IO must be directly involved in the allocation of USM resources to the HRPP.

5.0 Procedure

5.1. Goal and Objectives of the HRPP

5.1.1. The goal of the HRPP is to protect human research participants by ensuring that in all USM research:

5.1.1.1. The rights and welfare of human research participants are adequately protected.
5.1.1.2. Such research is guided by the ethical principles of respect for persons, beneficence, and justice as set forth in the Belmont Report, and is conducted with the highest level of expertise and integrity.
5.1.1.3. Such research complies with applicable laws.

5.1.2. The objectives of the HRPP are to:

5.1.2.1. Establish a formal process to monitor, evaluate, and continually improve the protection of human research participants and dedicate resources sufficient to do so.
5.1.2.2. Exercise oversight of research protection.
5.1.2.3. Educate investigators and research staff about their ethical responsibility to protect research participants.
5.1.2.4. When appropriate, intervene in research and respond directly to concerns of research participants.

5.2. Delegation of Responsibility for HRPP Implementation

5.2.1. The President of USM delegates, in writing, the authority and responsibility to the Provost of USM to establish, maintain, and oversee the HRPP, and designates the Provost as the IO.

5.2.1.1. This delegation includes but is not limited to:
5.2.1.1.1. Signing the FWA on behalf of USM.
5.2.1.1.2. Direct oversight of ORIO.
5.2.1.1.3. Direct oversight of the Institutional Review Board (IRB) including the appointment of Chairs and members.
5.2.1.1.4. Overseeing the protection of human participants, regulatory compliance, and implementation of the HRPP.
5.2.1.1.5. Ensuring that open channels of communication are maintained between the components of the HRPP.
5.2.1.1.6. Overseeing research investigators and staff.
5.2.1.1.7. Ensuring the independence of the IRB, including the authority to act without undue influence.
5.2.1.1.8. Ensuring that the HRPP is functional, adequately staffed and funded, and respected in the research community, including:
5.2.1.1.8.1. Annually reviewing the resources allocated to the HRPP.
5.2.1.1.8.2. Participating in the annual budget preparation of the HRPP.

5.2.1.1.8.3. Incorporating the HRPP budget into the USM budget.

5.2.1.2. The IO must have a basic understanding of the relevant laws, codes, regulations, and guidance that govern research involving human subjects, the responsibilities of an IO, and the responsibilities of the IRB and HRPP in protecting research participants.

5.2.2. The IO delegates the authority and responsibility to the RCA and ORIO to administer the HRPP.

5.2.2.1. This delegation includes but is not limited to:
5.2.2.1.1. The day-to-day operational responsibility for the HRPP and IRB.
5.2.2.1.2. Creating, establishing, and maintain the policies and procedures for the HRPP and related policies and procedures on behalf of USM.
5.2.2.1.3. Conducting periodic reviews of the HRPP in the context of continuous quality improvement activities.
5.2.2.1.4. Tracking and maintaining requested documentation for all open studies, even if ongoing IRB review is not required, using an IRB software or in-house database application if necessary.
5.2.2.1.5. Registering a new IRB, updating an existing IRB as required by federal regulations, and removing an IRB, in accordance with current OHRP guidance and instructions.

5.2.3. Through policies and procedures, the IO grants the IRB the authority to:

5.2.3.1. Approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization.
5.2.3.2. Suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.
5.2.3.3. Observe, or have a third party observe, the consent process and the conduct of the research.

5.2.4. The IRB is responsible and has the authority for prompt reporting to appropriate officials and entities in accordance with HRPP-034 Mandated Reporting to External Agencies.

5.3. Research Covered by the HRPP

5.3.1. All human subject research in which USM is engaged is covered by the HRPP.

5.3.1.1. An activity is covered under the HRPP when it meets the definition of human subject research, defined in HRPP-008 Determination of Activities Requiring IRB Review.

5.3.1.2. An activity is covered under the HRPP when it meets the definition of engaged, defined in this Standard Operating Procedure (SOP).

5.4. IRB Independence

5.4.1. The IRB functions independently of all other USM authorities.

5.4.2. No research involving human subjects may commence until the research has received all approvals required by the IRB.

5.4.2.1. Commencement of research involving human subjects without all approvals required by the IRB is an act of serious noncompliance to be addressed in accordance with HRPP-004 Noncompliance.

5.4.3. No individual, department, or authority at USM may approve research involving human subjects that have not been approved by the IRB.

5.4.4. IRB members report in a timely manner any potential undue influence on their decisions regarding the safety and welfare of research subjects in accordance with RCR-101 Alleged Research Misconduct.

5.5. Organizational Commitment

5.5.1. USM's Provost/ Vice President for Academic Affairs/Institutional Official is committed to dedicating resources and maintaining adequate support for the operations of the HRPP. The Provost meets regularly with the Assistant Provost of Research Integrity. USM agrees to provide the HRPP with meeting space and sufficient staff and resources to support its review, oversight, record-keeping and other duties.

5.5.1.1. The annual review will include an evaluation of the resources needed for the HRPP, including, but not limited to the following:

5.5.1.1.1. Staff;
5.5.1.1.2. Consultants;
5.5.1.1.3. IRB members;
5.5.1.1.4. Education program
5.5.1.1.5. Legal counsel
5.5.1.1.6. Assessing Conflict of interest
5.5.1.1.7. Maintaining a quality improvement plan
5.5.1.1.8. Community outreach
5.5.1.1.9. Meeting space;
5.5.1.1.10. Equipment;

5.5.1.1.11. Finances;
5.5.1.1.12. Information technology systems;
5.5.1.1.13. Space to store records;
5.5.1.1.14. Space to hold private conversations; and
5.5.1.1.15. Space to maintain computer and office equipment.

5.5.1.2. As part of the collaborative IRB model, the funds provided through external research protocol reviews are used to supplement resources of the HRPP operation, for example: provide additional education and networking experiences for ORIO staff and/or Board Members to attend conferences.

6.0 References

6.1. 45 CFR 46.101;

6.2. 45 CFR 46.103;

6.3. 21 CFR 56.106;

6.4. OHRP Guidance on Engagement of Institutions in Human Subject Research (2008).