UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-053
AAHRPP	Element I.1.A. and Standard I-9
Date Adopted:	
Last Updated:	
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Updated By:	
Reviewed By:	**IRB Chair; IRB; ORIO**
Procedure Title:	Review of Non-USM Protocols

1.0 Objective

1.1. To describe the primary ethical considerations applied to the review of research protocols conducted by investigators external to the University of Southern Maine (USM) and not covered by the USM Human Research Protection Program (HRPP).

2.0 Responsibility

2.1. Execution of this SOP is the responsibility of the Institutional Official (IO), Office of Research Integrity and Outreach (ORIO), Research Compliance Administrator (RCA), and Institutional Review Board (IRB) are responsible for executing this SOP.

3.0 General Description

3.1. The USM IRB(s) may review projects as a service to the general community to help foster academic and scientific efforts to pursue knowledge.

3.2. The USM IRB reviews protocols relating to human subjects research as defined by and in accordance with USM HRPP Policies and Procedures.

4.0 Definitions

4.1. **Principal Investigator (PI)** means an investigator who accepts overall responsibility for the research activity.

4.2. **External PI** means a principal investigator who is not a USM community member.

4.3. **USM community members** include officers, employees, agents, and students of the University of Southern Maine.

4.4. **Engagement** means that an institution's officers, employees, agents, and/or students, for the purposes of a research project, obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

4.5. **Key Research Personnel** are persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects' personal information.

4.6. **Research staff** are considered to be persons who 1) obtain data about living individuals for research purposes through intervention or interaction with them; 2) obtain individually identifiable private information for research purposes; and/or 3) obtain informed consent of human research participants.

5.0 Limitations

5.1. The USM IRB will review external protocols submitted by persons, agencies, and/or organizations under any of the following conditions:

5.1.1. USM personnel are involved in technical assistance or consulting roles;

5.1.2. The research is part of a multi-site or multi-state project, and other IRBs are reviewing each site/state portion of the project;

5.1.3. The PI has no IRB available to them;

5.1.4. The PI has no federally registered IRB available to them;

5.1.5. The PI's IRB has determined that, by its own criteria, a conflict exists which precludes it from conducting the review of the protocol;

5.1.6. The PI's IRB lacks the appropriate expertise to review the protocol;

5.1.7. The USM IRB is asked to provide a "second opinion" to another organization's IRB.

5.1.8. The project is a collaborative within the University of Maine System (UMS) pursuant to UMS policies.

5.2. Depending on its current membership, USM's IRB can review the following types of research protocols:

5.2.1. Social and behavioral research;

5.2.2. Biomedical research that is not considered a clinical trial (e.g., quality improvement projects, retrospective chart reviews, epidemiologic studies);

5.2.3. Humanitarian Use Device (HUD) clinical use for treatment or diagnosis consistent with approved labeling, emergency use for both off-label or approved label use, and compassionate off-label use; and

5.2.4. Emergency use of a drug or biologic.

5.3. Depending on its current membership expertise, USM's IRB can review the following topic areas of research:

5.3.1. Research involving protected or vulnerable populations, such as:

5.3.1.1. Minors;
5.3.1.2. Pregnant women;
5.3.1.3. Prisoners and
5.3.1.4. Individuals with a diminished capacity to give informed consent.

5.3.2. Research involving sensitive information, such as:

5.3.2.1. Information relating to sexual attitudes, preferences, or practices;
5.3.2.2. Information relating to the use of alcohol, drugs, or other addictive products;
5.3.2.3. Information pertaining to illegal conduct;
5.3.2.4. Information that, if released, could reasonably damage an individual's financial standing, employability, or reputation within the community;
5.3.2.5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
5.3.2.6. Information pertaining to an individual's psychological well-being or mental health;
5.3.2.7. Genetic information and
5.3.2.8. Projects that must obtain a Certificate of Confidentiality from the National Institutes of Health.

7.0 Procedures

6.1. Onboarding

6.1.1. PIs complete an online External IRB Review Request form.

6.1.2. ORIO schedules an introductory meeting to discuss the IRB submission process, necessary agreements, and fees.

6.1.3. A Service Agreement (SA) and an Institutional Review Board Authorization Agreement (IAA), depending on source of funding, is signed by the Signatory Officials of the PI's organization and USM.

6.2. Protocol Submission and Review

6.2.1. PIs must adhere to USM HRPP Policies and Procedures.

6.2.2. PIs and research personnel complete and keep current CITI training on human subjects or its equivalent and provide proof of completion.

6.2.3. PIs and research personnel request user IDs for the current online IRB submission platform.

6.2.4. PIs submit protocols for review following the current submission process outlined on the USM website.

6.2.5. The USM IRB reviews research protocols in accordance with USM HRPP Policies and Procedures.

6.3. Special Considerations

6.3.1. Protocol Monitoring

6.3.1.1. Entities submitting protocols for external review by the USM IRB agree to submit to periodic monitoring of their research by ORIO staff or IRB members. Designated representatives will monitor approved protocols for compliance with IRB recommendations by appropriate and reasonable means. This includes, but is not limited to:

6.3.1.1.1. Observation of the consent process,
6.3.1.1.2. Observation of the data collection process;
6.3.1.1.3. Appointment of a third party to undertake such observation;
6.3.1.1.4. Appointment of a third party to independently evaluate the PI's compliance;
6.3.1.1.5. Independent review of research documents, including but not limited to consent forms (both blank and completed) and research instruments;
6.3.1.1.6. Appointment of an IRB subcommittee charged with the monitoring process;
6.3.1.1.7. Request the PI(s) appear before a fully convened IRB for initial review and for any updates;
6.3.1.1.8. Request the PI(s) submit what data or analysis has been done to date to the IRB for review and

6.3.1.1.9. Ensuring that the PI possesses all required licenses, certifications, or other documentation necessary to conduct the proposed research and that all such records are current and valid.

6.3.2. Requirements

6.3.2.1. Any person or organization that is required by law to have its own IRB or use an IRB located in its jurisdiction must use the appropriate IRB first.

6.3.2.1.1. PIs must consult with or submit their protocol to their IRB (if applicable) or supply the USM IRB with a written statement justifying why the PI cannot use their own IRB.

6.3.2.1.2. The USM IRB's decisions/recommendations cannot be used to overrule another IRB's determinations.

6.3.2.2. Any organization that is mandated by law or other federal requirement to review its own research must contact the appropriate federal agency to see if external review by a third party is allowable and/or fundable (especially if a grant is involved) before contacting the USM IRB.

6.3.2.3. PI(s) and/or their organization(s) are solely responsible for ensuring that all key research personnel, support staff, etc. have any required licenses, certifications, or other documentation necessary to conduct the proposed research.

6.3.2.4. Any person or organization that is required by law to follow specific compliance requirements must also follow those requirements. IRB approval cannot exempt persons or organizations from complying with other regulations or obligations.

6.3.2.5. Neither USM nor the USM IRB can provide legal advice. When any issue or question requires legal advice, the PI must seek advice from independent legal counsel.

6.3.2.6. Any person or organization that is required to comply with Health Insurance Portability and Accountability Act (HIPAA) must have the proposed research reviewed by their own Privacy Officer for organizational compliance. USM's IRB can only review HIPAA-related issues as they apply to the proposed research.

7.0 Fees

7.1. In exchange for USM's services, USM charges fees based on a fee schedule to be applied per specific protocol review to cover reviewer time and administrative costs.

7.1.1. The current fee schedule can be found on the USM ORIO website.

7.2. If the potential protocol volume is substantial, a flat annual rate may be considered to reduce costs.

7.3. ORIO will bill all review fees via invoice, and payment is expected within 30 business days of invoice billing.

8.0 References

8.1. HRPP 008 Determination of Activities Requiring IRB Review (pdf)
8.2. HRPP 010 Exempt Determinations (pdf)
8.3. HRPP 014 Humanitarian Use Devices (pdf)
8.4. HRPP 015 Emergency Use (of drug, biologic, or device) (pdf)
8.5. HRPP 025 Initial and Continuing Review at IRB Meetings (pdf)
8.6. HRPP 026 Study Closure (pdf)
8.7. HRPP 027 Expedited Initial Review (pdf)
8.8. HRPP 028 IRB Reliance (pdf)
8.9. HRPP 030 Continuing Review (pdf)
8.10. HRPP 031 Education Requirements (pdf)
8.11. HRPP 035 Roles and Responsibilities of Investigators (pdf)
8.12. HRPP 040 IRB Review of Modifications (pdf)