

UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-003
AAHRPP:	Element I.1.A., Element II.3.C. & Element III.1.E.
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Procedure Title:	External Human Subject Research conducted within the USM Community

1.0 Objective:

- 1.1. To describe the policies and procedures for external principal investigators to engage the USM community on campus in research activities involving human subjects.

2.0 General Description

- 2.1. In accordance with federal and institutional regulations, prior to project initiation, the Office of Research Integrity and Outreach (ORIO) and/or Institutional Review Board (IRB) must approve any activity in which a University of Southern Maine (USM) community member is [engaged](#) in research involving human subjects. If the principal investigator is an external principal investigator, the investigator must follow the outlined procedures for recruiting USM community members as human subjects. No official of USM may approve the initiation of research involving human subjects if the research has not been approved by the ORIO/IRB [45 CFR 46.112].

3.0 Definitions

- 3.1. **Principal Investigator** means an investigator that accepts overall responsibility for the research activity.
- 3.2. **External Principal Investigator** means a principal investigator who is not a community member of the University of Maine system (UMS). A principal investigator from another University in the UMS should review the UMS Institutional Review Policy - *IRB Review of UMS Cooperative Research*.
- 3.3. **The University of Maine System (UMS):** Consists of seven Universities (University of Maine, University of Maine at Augusta, University of Maine at Farmington, University of Maine at Fort Kent, University of Maine at Machias, University of Maine at Presque Isle, University of Southern Maine).

- 3.4. **USM community members** include officers, employees, agents, and students of the University of Southern Maine.
- 3.5. **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.

4.0 **Responsibility**

- 4.1. It is the responsibility of USM community members, when approached by an external principal investigator wishing to recruit USM community members on campus or using campus-provided communication, to inform them of the institutional policy and direct them to ORIO staff.
- 4.2. ORIO staff will review all inquiries regarding external principal investigator recruitment of USM community members for research projects.
 - 4.2.1. Equity in recruitment and participation in research refers to all citizens, all those who are affected by research or who can benefit from its outcomes, should have equal opportunities to contribute to it.
- 4.3. The USM Provost has the authority to withdraw his or her institutional approval of the recruitment process or research project at USM at any time. If this occurs, the ORIO must be notified in writing.

5.0 **Regulations and Guidelines**

- 5.1. Title 45 CFR Part 46
- 5.2. University of Southern Maine [Policies, Procedures, and Guidance for Human Subject Research](#)
- 5.3. University of Maine System Institutional Review Policy – Section 601 [IRB Review of UMS Cooperative Research](#)
- 5.4. [University of Southern Maine Residence Hall Policies](#)

6.0 **Procedure**

- 6.1. **When relying upon another organization's IRB.** If working in collaboration with another institution/organization which has its own IRB, USM Investigators are permitted to request reliance of the outside IRB's determination or approval. A fully executed reliance agreement must be in place prior to the USM Investigator's initiation of any research activity approved by an external IRB. The Principal

Investigator (PI) is responsible for submitting all applicable material, including, but not limited to, Resume/CVs, current Collaborative Institutional Training Initiative (CITI) certificates or equivalent for all local investigator(s), a copy of the external research protocol, the study approval or determination letter from the external IRB, and/or consent forms. (See *HRPP-028 Reliance* and *HRPP-031 Educational Requirements*)

6.1.1. ORIO staff will then rely on all the materials provided to determine whether the research is exempt or expedited, and whether USM is engaged in the research project.

6.1.2. [USM/Collaborative IRB relying on another IRB's review and approval of your research project form.](#)

6.2. Where to make an inquiry. ORIO staff will receive all inquiries regarding external principal investigator recruitment of USM community members for research projects. It is the responsibility of the principal investigator to complete a reliance request form. ORIO staff will make a determination of whether USM is [engaged](#) in the research project. ORIO staff will require a copy of the research protocol and letter(s) of approval from outside institutions.

6.2.1. [External Human Subject Research conducted within the USM Form.](#)

6.3. When a project must have a USM Co-Principal Investigator. If the ORIO staff determines that USM *is* [engaged](#) in the research project, the project must include a USM Co-Principal Investigator before recruitment of USM community members as human subjects can begin. ORIO staff will advise, in writing, the external investigator, on the appropriate submission process, including any additional requirements. Recruitment of USM community members as human subjects must comply with the recruitment process reviewed and approved by the IRB.

6.4. When recruitment can occur without a USM Co-Principal Investigator. If the ORIO staff determines that USM *is not* [engaged](#) in the research project, the external principal investigator may recruit USM community members as human subjects. The IRB will evaluate recruitment processes, including advertisements, to ensure a fair and equitable selection of participants. Examples of the following outlets on USM property:

6.4.1. Flyers and posters on any USM campus in compliance with USM policies regarding advertisements from outside organizations;

6.4.2. Advertisement in the USM newspaper;

6.4.3. Request directory information from the USM Registrar, such as e-mail addresses, **unless an individual student has taken formal action to restrict its release** and/or

- 6.4.4. Request that a USM faculty or staff member forward an email recruitment letter to other USM community members on behalf of the external principal investigator.