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 Orono, University of Maine at Presque Isle, University of Maine at Somerset County).
University of Maine at Presque Isle, University of Southern Maine).

3.5 USM Community members include officers, employees, agents, and students of the University of Southern Maine.

3.6 Engagement means an institutions 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.

4.3 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-IRB Review of UMS Cooperative Research.

5.4 University of Southern Maine Residence Hall Policies

6.0 Procedure:

6.1 Where to make an inquiry. ORIO staff will receive all inquiries regarding external principal investigator recruitment of USM community members for research projects. ORIO staff will make a determination of whether USM is engaged in the research project. ORIO staff may request to see the research protocol and any letters of approval from outside institutions.

6.2 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 be reviewed and approved by the USM IRB before recruitment of USM community members as human subjects can begin. A USM Co-Principal Investigator must be added to the research project. 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.

6.3 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 through the following outlets on USM property:

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

2. Advertisement in the USM newspaper,

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

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