Procedure #:	HRPP-046
AAHRPP:	Element I.4.B. & Element I.4.C.
Date Adopted:	4/2/2021
Last Updated:	4/2/2021
Updated By:	
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Outreach and Community Involvement

1.0 Objective

1.1. To describe the policies and procedures for maintaining community outreach activities offered by the University of Southern Maine (USM) and the USM Institutional Review Board (IRB).

2.0 General Description

2.1. The Human Research Protection Program (HRPP) makes information and resources available to improve community awareness and involvement with research at USM to comply with the ethical principle of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), and Institutional Review Board (IRB) to execute this Standard Operating Procedure (SOP).

4.0 Procedure

4.1. Informed consent forms associated with research activities are to be reviewed and approved by the IRB to ensure that procedures are in place to facilitate the ability of research participants to ask questions, express concerns, or voice complaints to the HRPP, IRB, ORIO, or the Principle Investigator (PI).

4.2. USM enhances the understanding of human research with participants, potential participants, and communities, as appropriate, using a variety of methods. These include:

    4.2.1. Mandatory Statement on Communications and Consent Forms by the Principal Investigator:

4.2.1.1. If you have any questions or concerns about your rights as a research subject, you may call the USM Research Compliance Administrator at (207) 780-4517 and/or email usmorio@maine.edu. Information for research participants.

4.2.2. General and specialized research communications available on the NSF website;

    4.2.2.1 Risks of conducting Human Subjects Research

4.2.3. Internal resources for PIs to share with the research community on the ORIO website; or

    4.2.3.1. Recruitment Materials Guidance
    4.2.3.2. Program for Readability in Science and Medicine (PRISM)
    4.2.3.3. The Role and Responsibilities of the Faculty Advisor
    4.2.3.4. Dissertation Checklist

4.2.4. Individual or group meetings as requested.

4.3. For USM investigator-initiated research, investigators incorporate community input as appropriate in the design, implementation, and dissemination of research. Based on the type of research, investigators may employ one or more of the following methods:

4.3.1. Planned community sessions;
4.3.2. Community advisory groups;
4.3.3. Participant advocates; or
4.3.4. Partnerships with community-based organizations.

4.4. Principle Investigators make available information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives or their community to discuss concerns, raise questions, obtain information, complain about the research, or ask questions about rights as a research participant, or provide input on the design of future studies.

4.4.1. This information is available to all individuals who are going to participate in the human research protocol.

4.4.2. Contact information for reporting complaints or concerns is provided on the recruitment materials and consent forms; of which a copy is provided to research participants.

4.4.3. Research participants may contact HRPP, ORIO or IRB staff to provide feedback and/or obtain information about human subjects' research.

    4.4.3.1. ORIO contact information is found on the USM ORIO's website;

4.4.3.2. Contact information for ORIO staff members can also be found on the USM ORIO's website;

4.4.3.3. HRPP contact information is found on the U.S. Department of Health and Human Service's website.

4.5. Any form of participant communication received by HRPP, ORIO or an investigator will be acknowledged and forwarded to the appropriate individual within the organization for handling and to follow-up. While a prompt resolution is expected, the time-frame is dependent on the complexity of the complaint or concern.

4.6. Feedback from investigators and other research community members, the consent process, formal and informal evaluations, reviews and audits are used as input for improvements, including community awareness and outreach activities.

4.7. ORIO will periodically evaluate its community involvement activities and make changes, when appropriate, to improve outreach methods; adjust content and materials, and collaborate and educate others on updating such activities.

4.7.1. These evaluations take place in an informal, ongoing manner. ORIO staff will report both positive and negative feedback regarding community awareness and outreach activities to the Research Integrity Officer (RIO) or Assistant Provost for Research Integrity, whomever tracks the input and recommends changes to improve community involvement.

4.7.2. The Research Integrity Officer or Assistant Provost for Research Integrity will summarize the feedback annually to formally evaluate its outreach activities and determine:

4.7.2.1. The specific community outreach activities being used; and
4.7.2.2. Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these.