UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-036
AAHRPP:	Element I.1.D.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Standard Operating Procedures

1.0 Objective

1.1. To describe the policies and procedures for developing, reviewing, revising, and distributing standard operating procedures (SOP) for the University of Southern Maine (USM) Human Research Protection Program (HRPP).

2.0 Responsibility

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

2.2. The RCA or designee is responsible for writing SOPs.

2.3. Investigators are responsible for monitoring the ORIO website to ensure compliance with USM policies and federal regulations.

3.0 General Description

3.1. The ORIO maintains SOPs to ensure effective functioning of the USM HRPP.

3.2. The ORIO documents when SOPs are initiated, revised, and disseminated to ORIO staff, IRB members, and investigators.

3.3. All SOPs are in compliance with federal, state, and local laws and regulations.

4.0 Procedures

4.1. Writing SOPs

4.1.1. The RCA or designee, with advice from ORIO staff, IRB members, and/or investigators, determines when a new SOP needs to be established.

4.1.2. The RCA consults ORIO staff, IRB members, and/or investigators on IRB-related issues in developing the SOP.

4.1.3. If the SOP involves coordination with another USM office, the RCA cooperates with the office in drafting the SOP and routes the SOP to the appropriate individual representing that office for review.

4.1.4. ORIO staff ensure that each SOP designates the date on which it originally became effective as well as the most recent revision date.

4.2. Disseminating new SOPs

4.2.1. ORIO Staff monitor the SOPs and disseminate new SOPs to all ORIO staff and IRB members.

4.2.2. ORIO staff and IRB members are responsible for reviewing the new SOP and returning any comments to the RCA within a reasonable amount of time.

4.2.3. ORIO maintains the most recent versions of all approved SOPs on the ORIO website.

4.2.4. ORIO staff provide information on the availability of the SOPs through a variety of educational incentives.

4.3. Revising SOPs

4.3.1. The RCA or designee, with advice from ORIO staff, IRB members, and/or investigators, determines when to revise an existing SOP.

4.3.2. The RCA consults ORIO staff, IRB members, and/or investigators on IRB-related issues in revising the SOP.

4.3.3. If the SOP involves coordination with another USM office, the RCA cooperates with the office in revising the SOP and routes the SOP to the appropriate individual representing that office for review.

4.3.4. ORIO staff ensure that each SOP designates the most recent revision date.

4.3.5. Disseminating revised SOPs

4.3.5.1. ORIO Staff monitor the SOPs and disseminate revised SOPs to all ORIO staff and IRB members.
4.3.5.2. ORIO staff and IRB members are responsible for reviewing the revised SOP and returning any comments to the RCA within a reasonable amount of time.
4.3.5.3. ORIO maintains the most recent versions of all approved SOPs on the ORIO website.

4.4. Addendums

4.4.1. The RCA or designee has the authority to implement temporary contingency procedures that may differ from existing SOPs in emergency situations or during transitional periods.

4.4.2. The RCA will document temporary contingency procedures and the period in which they are in effect via an SOP addendum to the applicable SOP(s).

4.5. Reviewing SOPs

4.5.1. The RCA or designee conducts a periodic review, once a year, or according to workload or need, of the continuing suitability of the SOPs.

4.5.2. ORIO staff may also review SOPs at any time for accuracy and applicability.

4.5.3. ORIO staff obtain information necessary to update SOPs through the monitoring of sources including, but not limited to, the U.S. Food & Drug Administration and Office for Human Research Protection websites and email lists.

4.5.4. If applicable changes to SOPs become necessary, the RCA revises the SOP in question as soon as possible, following the procedures outlined above.

4.6. Suspension/Deletion

4.6.1. The RCA or designee has the authority to suspend or delete an SOP in such circumstances as major policy deliberation, changes in USM administration, or reorganization of departments, office, or community members with which the ORIO and IRB have coordinated relationships or joint procedures.

4.6.2. When an SOP is suspended or deleted, the RCA notes the date of such decision on the SOP.

4.6.3. ORIO staff remove the SOP from the ORIO website and archive the SOP as appropriate.

4.7. Record Keeping

4.7.1. ORIO staff maintain copies of all current SOPs in both hard copy and electronic files.

4.7.2. ORIO staff file SOPs in the SOP binder and place the electronic files into the SOP electronic folder.

4.7.3. ORIO staff file archive copies of all previous editions of SOPs in the SOP electronic folder.

4.7.4. ORIO maintains copies of original and subsequent revisions of all SOPs indefinitely.