UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	**HRPP 044**
AAHRPP:	Element I.5.A. & Element I.5.B.
Date Adopted:	
Last Updated:	May 31, 2021
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	**Quality Improvement/Quality Assessment**

1.0 Objective

1.1. To describe the policies and procedures that the University of Southern Maine's (USM's) Institutional Review Board (IRB) and the Office of Research Integrity and Outreach (ORIO) follow for administrative assessment and quality assurance/improvement of the Human Research Protection Program (HRPP).

1.2. ORIO conducts audits, surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. ORIO makes improvements to increase compliance, when necessary.

2.0 General Description

2.1. ORIO and the University of Southern Maine (USM) IRB is authorized to assess and implement quality improvement within its Human Research Protection Program.

2.2. ORIO and/or the IRB may periodically examine the effectiveness and/or efficiency of the institution's policies and procedures for protection of human subjects in research.

2.3. Materials to evaluate performance include, but are not limited to:

2.31. Board Chair and Vice Chair Evaluation;

2.32. Board Member evaluations: number and type of protocols, timeliness and efficiency of review;

2.3.3. ORIO & IRB Staff Evaluations;

2.3.4. Recordkeeping: Completeness of protocol submissions and meeting minutes;

2.3.5. Outreach activities/information: Community, Principal Investigator, board member, and staff feedback; or

2.3.6. Accreditation assessment tools used to evaluate the quality of ORIO's Human Research Protection Program and IRB process.

3.0 Definitions

3.1. Audit: An official examination of an organization's records and processes.

3.2. Quality Assurance: The maintenance of a desired level of quality in a service.

3.3. Quality Improvement: The framework used to systematically improve the ways services are delivered to customers/users.

3.4. Research Compliance Administrator (RCA): Individual that addresses adherence to rules, regulations, policies and standards of conducts that govern research.

3.5. Human Protections Administrator (HPA): Institutional employee that has comprehensive knowledge of all aspects of the institution's system of protections for human subjects and plays a key role in ensuring that the institution fulfills its responsibilities under its federalwide assurance with the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Human Protections Administrator (HPA), Institutional Review Board (IRB), principal investigators and research staff to execute this SOP.

5.0 Procedures

5.1. Administrative Assessment: An administrative assessment may require the selection of specific protocols for examination of a variety of topics including, but not limited to: review type, funding source, off-site research, event types, special research categories, specific IRB members, and/or assigned ORIO Staff

5.1.1. After identifying the protocols and/or related materials for examination, the Research Compliance Administrator (RCA) or designee conducts an in-depth review of either the IRB records for each identified protocol or related materials.

5.2. Assessment of Human Subject Research (HSR) Determination: ORIO Staff conducts annual assessments of human subjects' reviews including the number of reviews submitted, the length of time from protocol submission to approval, and the Principal Investigator (PI) submitting the protocols.

5.2.1. HSR Determination Statistics will be shared with IRB Board members annually.

5.3. Assessment of Exempt Review: ORIO Staff is responsible for assessment of exempt reviews. Annual assessment of exemptions granted will include the number of protocols

submitted, the length of time between protocol submission and approval, and the PI submitting the review.

5.3.1. Exempt Review protocol Statistics will be shared with IRB Board members annually.

5.4. Assessment of Expedited Review: ORIO Staff is responsible for assessment of expedited reviews. Annual audit of expedited reviews granted will include the number of protocols submissions, the length of time between submission and approval, and the PI submitting the review.

5.4.1. Expedited Review Protocol Statistics will be shared with IRB Board members annually.

5.5. Assessment of Risks and Benefits: If the RCA conducts an assessment of the IRB's determination of risk versus potential benefit of a protocol, including designation of minimal risk when appropriate, they verify the documentation in the research records which includes, but is not limited to:

5.5.1. Documentation in the meeting minutes or IRB records of the IRB's evaluation of risks of the research;

5.5.2. Determination of risk level;

5.5.3. Determination of the risk level of investigational device, if applicable;

5.5.4. Determination of minimized risks to participants; or

5.5.5. Appropriate disclosure of risks and benefits in the informed consent process.

5.6. Elements of Informed Consent Evaluation: When IRB members conduct a review to evaluate appropriate inclusion of the elements of informed consent, they verify adherence to the required elements of informed consent according to USM IRB Policy using the Consent/Assent Checklist as a guide.

5.6.1. Upon completion of the informed consent evaluation, the HPA will review the IRB's findings before disseminating the results to the principal Investigator.

5.6.2. If the informed consent evaluation identifies deficiencies, the HPA will provide a CITI-Training refresher course and in-person guidance to the principal investigator on the elements of informed consent.

5.7. Assessment for Appropriate Representation and Expertise for Vulnerable Population Protocol Review: If the HPA conducts an assessment for appropriate representation and expertise for a full board review of research involving vulnerable

populations (e.g., children, prisoners, pregnant women), they must verify the appropriate IRB member(s) who attended the convened meeting.

5.8. Evaluation of IRB Member Performance: The RCA, along with the HPA, and/or designee will meet with the Chair and Vice Chair of the IRB to review the results, recognize the board members' contributions and strengths, and make arrangements to assist the board members in any identified areas of needed improvement. (See *HRPP 021 IRB Board Composition and Membership.)*

5.8.1. Information to evaluate the IRB member include, but not limited to:

5.8.1.1. IRB Member participation/service;
5.8.1.2. Ability to apply knowledge of the federal regulations and ethical principles that serve as guidelines for responsible research; or
5.8.1.3. Competence in expedited and exempt reviews.

5.8.2. If applicable, one month before the expiration of an IRB board member term, the HPA will meet with ORIO staff to discuss renewal and performance improvements.

5.9. Evaluation of ORIO Staff: The RCA and ORIO staff will receive annual performance reviews by their applicable supervisor.

5.10. Human Research Protection Evaluation: At least every five (5) years, the HPA will establish a formal process to monitor, evaluate, and continually improve the protection of human research participants and dedicate resources sufficient to do so.

5.10.1. ORIO staff, RCA, or the IRB may participate in this assessment process.

5.10.2. Throughout this assessment, the HPA, RCA, or IRB members may determine the need for any revisions to current HRPP policies, procedures, and/or practices.

6.0 References

6.1. Association for the Accreditation of Human Research Protection Programs (AAHRPP)

6.2. U.S. Department of Health & Human Services (HHS) Office of Human Research protections (OHRP)

6.3. University of Southern Maine IRB policies and procedures