UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-040
AAHRPP:	Element II.2.E.3. & Element II.2.F.3.
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Procedure Title:	**IRB Review of Modifications**

1.0 Objective

1.1. To describe the policies and procedures for the Institutional Review Board (IRB) review of modifications for the University of Southern Maine (USM) Human Research Protection Program (HRPP).

2.0 General Description

2.1. Principal Investigators (PI) may not initiate any changes in research procedures or consent/assent form(s) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Examples of modifications that require IRB review include, but are not limited to:

2.1.1. Research personnel;
2.1.2. Recruitment Materials;
2.1.3. Subject populations;
2.1.4. Research procedures;
2.1.5. The location where research will be conducted;
2.1.6. Consent/assent forms;
2.1.7. Recruitment procedures; or
2.1.8. Date for completion of research.

2.2. If the PI makes and implements changes without prior IRB approval in order to eliminate apparent hazards to the subject(s), the investigator must immediately report the changes to the IRB. The IRB will review the changes and make a determination as to whether the changes are consistent with the subject's' continued welfare.

2.3. PIs must promptly notify the IRB in writing of any change in protocol status, such as discontinuation or completion of a research.

3.0 Definitions

3.1. **Modifications** are any changes that impact the overall protocol. Modifications may also be referred to as revisions or amendments.

3.2. **Minor Modifications** are a proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the research and does not substantially change the specific aims or design of the research. For example, but not limited to:

3.2.1. research personnel changes;
3.2.2. increase or decrease in proposed human research subjects' enrollment;
3.2.3. addition or deletion of qualified investigators; or
3.2.4. narrowing the range of the inclusion criteria).

3.3. **Significant Modifications** are a proposed change in research related activities that significantly affects an assessment of the risks and benefits of the research or substantially changes the specific aims or design of the research. For example, but not limited to:

3.3.1. broadening or narrowing the range of inclusion criteria,
3.3.2. the addition of a qualified research staff with a conflict of interest; or
3.3.3. extending substantially the duration of exposure to the test material.

4.0 Responsibility

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

5.0 Procedure

5.1. Submission of Modifications

5.1.1. The PI is responsible for submitting a modification request to USM IRB prior to the implementation of any change.

5.1.2. The PI will update or alter the sections of the IRB application as applicable.

5.1.3. A modification request must include all approved documents unless the document is being updated as part of the modification request. To modify an existing research;

5.1.3.1. Using a different color font or track changes. Editing of all applicable sections of the previously approved application will be done in a Word Document or PDF.

5.2. Screening of Submissions of Modifications

5.2.1. IRB staff screen the modification request for completeness and accuracy. IRB staff requests additional information from the PI as necessary.

5.2.2. IRB staff determines if the modification involves use of a medical device under Federal Food and Drug Administration (FDA) jurisdiction (i.e. collecting safety or efficiency data) if the request changes reference an instrument, apparatus, reagent, machine, implement, and/or device. If so, IRB staff screen the application to ensure the PI has provided all relevant materials (e.g., device labeling, modifications, risk justification), and include FDA language in the informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorizations.

5.2.3. IRB staff will consult applicable sources to determine if the modification involves use of or testing of products under FDA jurisdiction (i.e., use beyond the course of medical practice) if the requested change references a drug, biologic, therapeutic dietary supplement, substance affecting structure or function of the body, and/or product intended to diagnose, cure, mitigate, treat, or prevent disease. If so, IRB staff ensure the PI has provided all relevant materials (e.g., product labeling, investigator brochure) and include FDA language in the informed consent and HIPAA authorization.

5.2.4. IRB staff will ensure relevant materials are available for IRB review as needed if the modification adds vulnerable populations or requires documentation of specific regulatory findings.

5.2.5. IRB staff may also secure additional review depending on the nature of the requested change, if applicable. The IRB reviewer in such cases is responsible for applying the relevant regulatory requirements or ethical principles.

5.2.6. IRB staff screen changes to consent/assent forms for apparent issues (e.g., use of incorrect/unapproved versions). IRB staff will alert the IRB reviewer of any omissions or inconsistencies. The IRB has final authority for requiring consent/assent changes.

5.2.7. IRB staff screen changes to research personnel to ensure that all new research personnel has completed the required human subject protection Collaborative Institutional Training Initiative (CITI) training. If research personnel has not completed the required training, IRB staff inform the PI that the request cannot be approved by the IRB until the required training has been completed. IRB staff may ask the PI whether they wish to remove the research personnel in question from the modification request. Alternatively, the PI may choose to wait for approval until the research personnel in question to complete the training. In that case, IRB staff assigned the modification request to the IRB after the research personnel training has been completed. (Reference HRPP -031 Education Requirements).

5.2.8. IRB staff may review and approve minor modifications. Significant modifications are reviewed by the IRB Chair or another qualified IRB member as the primary reviewer.

5.2.9. For USM research, the IRB staff, in collaboration with the University System Information Security Office screen for compliance with HIPAA regulatory requirements.

5.3. Expedited Review Modification Procedures

5.3.1. PIs may request an IRB review of their modifications by creating an amendment in the online submission system. All protocols that the IRB review will be analyzed for eligibility to use an expedited review procedure in accordance with the expedited review criteria. Attach applicable additional materials.

5.3.2. The IRB Staff and the IRB will attempt to act on a request for modification review within ten (10) working days of receipt modification.

5.3.3. In an expedited review, an IRB reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove of the research in its entirety. If the reviewer does not find that the proposed modifications exceeds the criteria for expedited review, the proposal will be reviewed using a full review procedure.

5.4. Full Review Modification Procedures

5.4.1. IRB staff place a modification request on an agenda for a convened meeting, when the modification request involves changing the risk level to more than minimal risk, an IRB Chair or designated IRB member recommends full review. The sponsor or PI of the research can specifically request full review of the modifications.

5.4.2. IRB staff invite the PI to attend the meeting if the IRB requires that they attend. The full IRB reviews of the modification request and applies the Federal criteria for approval as applicable to the request.

5.4.3. Approximately one week prior to the convened IRB meeting, IRB staff closes the agenda. The modification request and the protocol materials affected by the proposed modification will become available to the full board for review.

5.4.4. The IRB Chair or designated IRB member who serves as the primary reviewer reports recommendations to the IRB at the convened meeting. The IRB Chair or designated IRB member makes recommendations on issues they determine do not meet the Federal criteria for approval, involves controverted issues, or needs additional information. If the IRB Chair or designated IRB member is unable to attend the meeting, written comments, or recommendations are provided to the IRB at the convened meeting.

5.4.5. The convened IRB reviews and votes on the modification request. The IRB Chair or designated IRB member documents the IRB determination in the online submission system.

5.5. Review Outcomes

5.5.1. IRB staff will notify the PI of the IRB's decision by letter.

5.5.2. The end date of the protocol approval period remains the same as that assigned during initial or continuation review when the IRB approves a modification.

5.5.3. If the PI has concerns regarding the IRB decision; recommendations for changes in the research, they may submit their concerns via a written appeal that includes justification for changing the IRB decisions. The PI sends the request to the IRB staff to be shared with the reviewer, IRB Chair, or convened IRB review the appeal. The appeal determination is final.

5.5.4. It is the responsibility of the PI to notify and /or provide materials to participants if any significant new findings arise from the review process where the participants might withdraw their willingness to continue participation

6.0 References

6.1. 45 CFR 46.103;

6.2. 21 CFR 56.110(b)(2);

6.3. 45 CFR 46.110(b)(2);

6.4. 45 CFR 46.111;

6.5. 21 CFR 65.111;

6.6. 21 CFR 312; and

6.7. 21 CFR 812.