UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-030
AAHRPP:	Element II.2.E.2., Element II.2.E.3, Element II.2.F.2.
Date Adopted:	8/24/2020
Last Updated:	4/28/2020
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Updated By:	
Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	**Continuing Review**

1.0 Objective

1.1. To describe the policies and procedures for the University of Southern Maine (USM) Institutional Review Board (IRB) for conducting continuing review (CR) of human subjects research.

2.0 General Description

2.1. The IRB has determined that a CR of research is required for all research that qualifies for expedited review due to the unique nature of a multi-institution Collaborative IRB.

2.2. The IRB conducts substantive and meaningful CR for research requiring full board or expedited review.

2.2.1. The research protocol must satisfy the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111 for the IRB to approve the protocol for continuation.

2.2.2. If the IRB approves research with conditions:

2.2.2.1. If the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.

2.3. The IRB approval period for research requiring full board or expedited review can extend no longer than one (1) year after the start of the approval period.

2.3.1. Investigators may not continue research activities after the expiration of IRB approval; continuation is a violation of federal requirements specified in 45 CFR 46.103(a) and 21 CFR 56.103(a).

2.3.2. If the IRB approval expires, the PI must cease all research activities and may not enroll new subjects in the study.

2.3.2.1. However, if the IRB determines there is an overriding safety concern and/or ethical issue or that it is in the best interests of the individual subjects to continue participating in the research activities, the IRB may permit the subjects to continue in the study for the time required to complete the CR process.

2.3.3. The IRB may determine continuing review should occur at an interval less than one year when:

2.3.3.1. Required by other applicable regulations (e.g., FDA);
2.3.3.2. Required by the terms of a grant, contract, or other agreement
2.3.3.3. The research involves topics, procedures, or data that may be considered sensitive or controversial;
2.3.3.4. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
2.3.3.5. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
2.3.3.6. An investigator has a history of noncompliance.

2.4. Research originally reviewed and approved by full board or expedited procedures continues to undergo CR review until one of the follow criteria are met:

2.4.1. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects;

2.4.2. Study personnel have enrolled no subjects at USM and no additional risks have been identified either at USM or at any site if the research involves a multi-site study;

2.4.3. The only remaining research activities are limited to data analysis; or

2.4.4. The IRB determined and documented at a convened meeting that the research is not greater than minimal risk, no additional risks have been identified, and:

2.4.4.1. The research involves the study of drugs and does not require an Investigational New Drug (IND) (21 CFR Part 312);
2.4.4.2. The research involves the study of medical devices and does not require an Investigational Device Exemption (IDE) (21 CFR Part 812); or
2.4.4.3. The research involves the study of medical devices and the device is approved for marketing and being used in accordance with the approved labeling.

3.0 Responsibility

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

4.0 Procedure

4.1. Submission and Screening

4.1.1. The principal investigator (PI) submits a completed IRB continuing review application to the ORIO.

4.1.1.1. There is one continuing review form for all research regardless of the applicable review categories.

4.1.2. Upon receipt of the application, ORIO staff screen the application including the informed consent process and documentation for completeness and accuracy.

4.1.2.1. If it is clear to the designated ORIO staff that the application does not require continuing review, the designated ORIO staff contacts the PI and recommends a final report be submitted.
4.1.2.2. ORIO staff contact the PI for any additional information needed for a thorough review.

4.1.3. After screening the application, ORIO staff send the application to the RCA or designee to assign a reviewer.

4.2. Assigning a Reviewer

4.2.1. The RCA or designee makes the IRB primary reviewer assignment (a minimum of one (1) IRB member from among the IRB membership) based on the member's familiarity with the particular protocol and his/her experience and expertise.

4.2.1.1. Reviewers notify ORIO staff if they are unable to conduct a continuing review during the assigned time period or have a conflict of interest as outlined in *HRPP-023 IRB Member and IRB Staff Conflict of Interest*.
4.2.1.1.1. If this occurs, another reviewer is selected by the RCA.
4.2.1.2. At least one IRB member is provided and reviews the complete protocol including any protocol amendments previously approved by the IRB.

4.3. Review Procedure

4.3.1. The IRB primary reviewer of a full board or expedited protocol receives a completed continuing review application which includes the following:

4.3.1.1. The brief project summary;
4.3.1.2. A progress report;

4.3.1.3. The current IRB approved consent document or any newly proposed consent documents;
4.3.1.4. Any materials related to requested current amendments of the research;
4.3.1.5. Number of participants accrued;
4.3.1.6. A summary since the last IRB review of:
4.3.1.6.1. Adverse events, untoward events, and adverse outcomes experienced by participants;
4.3.1.6.2. Unanticipated problems involving risks to participants or others;
4.3.1.6.3. Participant withdrawals;
4.3.1.6.4. The reasons for withdrawals;
4.3.1.6.5. Complaints about the research;
4.3.1.6.6. Amendments during the last approval period; and
4.3.1.6.7. Any relevant recent literature.
4.3.1.7. Any interim findings;
4.3.1.8. Any data and safety monitoring reports;
4.3.1.9. Any relevant multi-center trial reports; and
4.3.1.10. The researcher's current risk-potential benefit assessment based on study results.
4.3.1.11. Any recruitment materials.

4.3.2. For expedited protocols, the reviewer is responsible for reviewing the application upon receipt using the federal criteria for expedited review as outlined in the *HRPP-027 Expedited Initial Review*.

4.3.3. For full board protocols, the reviewer and convened IRB is responsible for reviewing the application upon receipt using the federal criteria for full board review as outlined in the *HRPP-025 Initial and Continuing Review at IRB Meetings*.

4.3.4. The PI will be notified by letter of the Board's decision.

5.0 References

5.1. 21 CFR 56.108(a)(1)&(2);
5.2. 21 CFR 56.109(f);
5.3. 21 CFR 56.110; 21 CFR 56.111;
5.4. 21 CFR 56.115(a)(3)&(7);
5.5. 45 CFR 46.108;
5.6. 45 CFR 46.109(f);
5.7. 45 CFR 46.111;
5.8. 45 CFR 46.115(a)(3)&(7);
5.9. 45 CFR 160;
5.10. 45 CFR 164.