UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-031
AAHRPP:	Element I.1.E., Element II.1.B. & Element III.2.A.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	**Education Requirements**

1.0 Objective

1.1. To describe the training requirements and education opportunities for individuals who are Principal Investigators (PI), Research Staff, and Institutional Review Board (IRB) Members to appropriately educate about the regulatory requirements and ethical considerations for research.

2.0 General Description

2.1. The foundation for the effective implementation of all facets University of Southern Maine (USM) Human Research Protection Program (HRPP) and for efforts to promote compliance with HRPP requirements lies in a comprehensive, mandatory education program for all Principal Investigators, Research Staff, and Office of Research Integrity and Outreach (ORIO) IRB Members.

3.0 Definitions

3.1. Collaborative Institutional Training Initiative (CITI) is a subscription service that provides research ethics education to the members of the research community.

3.2. Shadow Review means that the IRB Member is able to observe the initial application review process between the researchers and the IRB Members assigned to review the application.

3.3. Research staff are considered to be persons who 1) obtain data about living individuals for research purposes through intervention or interaction with them; 2) obtain individually identifiable private information for research purposes; and/or 3) obtain informed consent of human research participants.

4.0 Responsibility

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

4.2. The HRPP is responsible for ensuring the protection of the rights and welfare of persons participating in human subject research conducted at or affiliated with the USM.

4.3. All PIs and Research Staff conducting Human Subject Research (HSR), ORIO IRB Members, and the ORIO staff are responsible for:

4.3.1. Completing the required initial human subjects training and refresher training, as well as maintaining documentation of such certification, as specified in this policy.

4.3.1.1. Reference *HRPP-021 IRB Composition* and *Membership* and *HRPP-035 Roles and Responsibilities of Investigators*.

4.3.2. Complying with any additional training requirements set forth within the USM IRB (e.g., Institute or Center training requirements: (pdf version) https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/mandated-training-scientific-staff-working-nih-facilities).

4.3.3. Provide a copy of their current resume/CV.

5.0 Procedure

5.1. Principal Investigators and Research Staff

5.1.1. Human Research Protection Education: Investigators and Research Staff

5.1.1.1. PIs, research staff, and any individual engaged in human research overseen by the USM IRB must complete and maintain current Human Subject Research Protection CITI training.

5.1.1.2. PI Responsibility

5.1.1.2.1. Ensuring that all individuals on the research team have completed training prior to engaging in research with human subjects;

5.1.1.2.2. Evaluating the knowledge and skills of all researchers involved in conducting research with human subjects on studies for which they are responsible; and

5.1.1.2.3. Providing documentation of required training to the ORIO.

5.1.2. Initial Human Research Protection Training

5.1.2.1. New or current investigators and research staff receiving their first Human Subject Research Protection training are required to complete the requisite training modules of the Collaborative Institutional Training Initiative (CITI) courses. The ORIO website and/or ORIO staff will provide instructions on accessing and using CITI modules.

5.1.2.2. ORIO may accept a comparable CITI training from another institution.

5.1.2.3. Trainings from an alternative platform other than CITI are reviewed on a case-by-case basis.

5.1.3. Continuing Human Research Protection Training

5.1.3.1. The requisite CITI refresher modules are required to be completed once every four years.
5.1.3.2. Supplemental Human Research Protection training may be required, initially or as a continuing requirement, by the IRB when appropriate (e.g., for research that involves vulnerable populations, such as when based on results of a post-approval monitoring visit).
5.1.3.3. Investigators may request that the IRB provide education on specific relevant topics needed by the investigators and research team.
5.1.3.4. Failure to fulfill requirements will result in individuals not being able to engage in human subject research until the appropriate training has been completed.
5.1.3.4.1. The IRB may not approve, may not provide continuing approval, or may suspend research when education requirements are not fulfilled in a timely manner.
5.1.3.4.2. PIs are responsible for ensuring that individuals engaged in their research project obtain and maintain relevant and appropriate training.
5.1.3.4.3. The submitted protocol will provide the records of educational fulfillment by investigators and research staff.

5.2. IRB Members and Staff Procedure

5.2.1. IRB Members and Staff will be trained through an initial orientation process and continuing education to ensure that all IRB Members and Staff are appropriately educated and knowledgeable about the regulatory requirements, USM policies, and procedures, and ethical considerations for the protection of human subjects involved in the research.

5.2.2. Orientation of IRB Members and Staff: New IRB Members are required to complete an orientation process prior to reviewing any human research studies. New Member orientation includes meetings with the IRB Chair and RCA.

5.2.2.1. Any new IRB staff will be trained by the RCA and IRB Chair. The focus of the meetings will include:
5.2.2.1.1. Human Research Protection Program at USM;
5.2.2.1.2. U.S. regulations that pertain to human subject research;
5.2.2.1.3. International regulations that pertain to human subject research;
5.2.2.1.4. Key issues in the protection of human subjects; and
5.2.2.1.5. Day-to-day operations of the ORIO and IRB.
5.2.2.2. New IRB Members and Staff are required to complete the required training modules of the Collaborative Institutional Training Initiative

(CITI) courses, as: IRB Member, Social and Behavioral and/or Biomedical trainings.

5.2.2.3. New IRB Members will perform a minimum of one "shadow reviews" of new initial applications.

5.2.2.4. The orientation procedure for the IRB Chair will be performed by the RCA and will vary by level of IRB experience and familiarity with the USM IRB review process.

5.2.3. The IRB will provide and support continuing educational opportunities. The IRB ongoing implementation of additional continuing education activities at regularly scheduled IRB Member meetings.

5.2.3.1. CITI Training is required for IRB Members and Staff once every four years of IRB service.

5.2.3.2. At convened IRB Meetings, the IRB Chairs may disseminate updates, guidance, and other materials containing ethical and regulatory guidance for the review of protocols, including in specialized areas or selected vulnerable subject populations (e.g., children, pregnant women). In some cases, the education segment may be aimed at issues related to specific challenging research being reviewed by the USM IRB.

5.2.3.2.1. Continuing education presentations or discussions will typically be provided at the convened IRB meetings. The educational materials are provided a week ahead of the convened meeting. The presentation will typically last 15-45 minutes. Presentations may be provided by the RCA, the IRB Chair, Members, or others. Presentations may focus on topics specific to items on the agenda. IRB Members are encouraged to contact the RCA or IRB Chair with topic suggestions.

5.2.3.2.2. Records of the training will be documented in the IRB minutes. The IRB administrator will make available any continuing education material distributed at the IRB meeting so that non-attendees of the IRB meeting may access the materials.

5.2.3.3. An IRB retreat that brings all IRB Members and Staff together may be considered continued education and discussions of IRB function and improvements.

5.2.3.4 The IRB may subscribe to journals and news services related to human research protections, as appropriate.

5.2.3.4.1. IRB Members and Staff may also subscribe to relevant list-serves; such as IRB Forum <irb_general@irbforum.org>

5.2.3.5. The RCA will collect and maintain a listing of relevant resources and educational materials such as articles, books, and Internet resources on human research protection. IRB Members may access and borrow hard copies, such as where these are cataloged in the ORIO Library.

5.2.3.6. IRB Members are encouraged to participate in continuing education conferences and webinars. They may also receive educational information via email.

5.2.4. Fulfillment of Requirements: IRB Members' participation in educational events will be recorded and maintained by the ORIO.

5.2.4.1. On an annual basis, education requirements and IRB Members' achievement of them are evaluated by the IRB Chair, with assistance from the RCA. The IRB Chair and/or the RCA will work with IRB Members who may need additional IRB training within allotted time frames to assure that continuing education requirements are met.

5.2.4.1.1. The IRB Chair will initiate corrective actions that may include not being involved in reviewing research studies or attending IRB meetings until the delinquent requirement is satisfied.

5.2.4.2. Educational needs will be identified in yearly IRB Member evaluations.

5.2.4.3. If an IRB Chair or IRB Member does not fulfill his or her initial and or continuing education requirements, the Institutional Official may require removal.

5.2.5. "Experienced" Reviewer Designation for Expedited Review: The IRB Chair will determine whether the member is experienced or if the further experience is needed. If the IRB Member is deemed experienced, the IRB Chair shall notify the IRB Member in writing of the determination. If the IRB Member is not deemed to be experienced, additional training will be required as appropriate. The RCA will maintain a list of experienced IRB Members, in consultation with the IRB Chair, assign protocol for review accordingly.

5.2.5.1. To be designated as an "experienced" IRB Member, the IRB Chair will evaluate the IRB Member in light of:

5.2.5.1.1. The completion of the orientation process.

5.2.5.1.2. Involvement in at least one study, where practicable, as a shadow reviewer on expedited protocols;

5.2.5.1.3. Attendance and thoughtful contributions at two or more convened meetings; and

5.2.5.1.4. Previous IRB experience, if any.

5.2.5.2. The RCA and Staff should be encouraged to obtain national certification relevant to their position. Continuing education is expected to maintain certification; otherwise, the individual must typically retake the certification exam.

6.0 References

6.1. 21 CFR 56.110(b);
6.2. 45 CFR 46.110(b)(2).