UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-028
AAHRPP:	Standard I-9, Element II.2.E.3., Element II.2.I. & Element II.5.B.
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Procedure Title:	IRB Reliance

1.0 Objective

1.1. To describe policies and procedures for how the rights and welfare of research participants are protected when the University of Southern Maine (USM) Collaborative Institutional Review Board (IRB) is sharing oversight of research with another organization.

2.0 General Description

2.1. USM has established procedures to define the responsibilities of each institution, coordinate communication among responsible IRBs, promote compliance of all involved institutions and investigators, and manage information shared in external or multi-site research to ensure the protection of human subjects.

2.2. The Office of Research Integrity and Outreach (ORIO) staff take into consideration the source of funding for the research activity, federal regulations, specific sponsor regulations governing human research protections, and institutional policy.

2.3. USM may enter into formal reliance agreements with other institutions that are not legal entities of USM to provide research review (i.e., to act as the Reviewing IRB), to rely on other institutions for research review, or to share IRB review.

2.4. USM enters into these types of reliance agreements through a Service Contract (SC), IRB Authorization Agreement (IAA), External Review Agreement (ERA), or other written contract with the institution(s) in question.

3.0 Definitions

3.1. IRB Authorization Agreement (IAA) means an agreement that identifies and describes the respective authorities, roles, responsibilities, and methods of communication between an institution/organization providing the ethical review of research and a participating site relying on the institution/organization.

3.2. **Single IRB (sIRB)** means the selected IRB of record that conducts the ethical review of research for all participating sites of a multi-site study under purview of the National Institutes of Health (NIH).

3.3. **Federalwide Assurance (FWA**) means a formal, written, binding attestation in which an institution ensures to the U.S. Department of Health and Human Services (DHHS) that it will comply with applicable regulations governing the protection of human subjects.

3.4. **Institutional Official (IO)** means the signatory on the FWA filed with the Office for Human Research Protections (OHRP).

3.4.1. OHRP requires the IO to be a high-level official who has the authority to represent the institution named in the FWA.

3.4.2. The Provost serves as the IO for USM and is responsible for signing reliance agreements on behalf of the institution.

3.5. **Multi-site research study** means the same protocol is used to conduct non-exempt human subjects research at more than one site.

3.6. **Participant site** means the organization that will rely on the IRB of another institution/organization (a.k.a. an external IRB) to carry out the IRB review of human subjects research for a multi-site study.

3.7. **Relying IRB** means the organization that will rely on the review of, or has ceded IRB review to, another IRB to provide oversight for a specific research study or set of studies.

3.7.1. This process is also is referred to as deferring IRB review.

3.8. **Reviewing IRB** means the IRB of record or the IRB that provides the ethical review of the research.

4.0 Responsibility

4.1. 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.

5.0 Procedure

5.1. When USM serves as the Reviewing IRB:

5.1.1. When a USM principal investigator (PI) requests that the USM IRB serve as the Reviewing IRB for a non-USM research site, the PI submits a USM specific protocol for review and approval prior to the addition of non-USM sites.

5.1.1.1. USM's HRPP will serve as the reviewing IRB for determinations of exempt activities or activities deemed to be not human subject research on a case-by-case basis.

5.1.1.2. Requests for adding sites to an approved protocol will be submitted by the PI as an amendment to USM's IRB.

5.1.1.2.1. If the amendment to add sites does not increase the risk to research participants, the amendment will be considered a minor modification.

5.1.2. ORIO Staff determine on a case-by-case basis whether to review the site additions as separate protocols or as modifications to the previously approved research. USM/Collaborative IRB would be relying on another IRB's review and approval of your research project (Google form)

5.1.2.1. If a site is added through a modification, the RCA or designee decides whether to handle such a modification using expedited review procedures or the convened IRB for review.

5.1.3. The relying site provides the ORIO with general information using the External IRB Review Request form.

5.1.3.1. IRB applications and other materials must contain a description of any laws relevant to the study being reviewed by the IRB when research is conducted in another state.
5.1.3.2. Information about relevant laws may be provided in a memorandum of understanding, research site agreement, local context form, or other ways.

5.1.4. The USM IRB reviews the following issues for all relying sites, and ensures reporting of such events in accord with the requirements specified in the reliance agreement or pursuant to Federal, state or local regulations:

5.1.4.1. Suspension or termination of IRB approval; and
5.1.4.2. All unanticipated problems involving risks to participants or others; and
5.1.4.3. Requests for audits of research protocols.

5.1.5. The USM IRB does not review Health Insurance Portability and Accountability Act (HIPAA) of 1996 for organizations outside of USM's covered entity.

5.1.5.1. Each reviewing site complies with their institution's HIPAA policies and procedures.

5.1.6. The USM IRB notifies the investigators (and if applicable, the external organization) of its review decisions consistent with any reliance agreement.

5.1.7. The USM IRB makes available relevant IRB records, including (but not limited to) minutes, approved protocols, consent documents, and other records that document the IRB's determinations to the relying organization upon request.

5.1.8. The ORIO website contains relevant IRB SOPs readily available to the relying organization. The ORIO communicates updates via email, which is distributed to all USM investigators.

5.1.9. The USM investigator is responsible for forwarding any applicable updates to collaborators at relying organizations.

5.1.10. The USM IRB provides contact information to investigators/research staff to use for answers to questions, express concerns, and convey suggestions regarding the IRB review.

5.1.11. The USM IRB will request from the relying organization whether additional reviews will be conducted by an external organization, including but not limited to biosafety review, radiation safety review, recombinant DNA research review, human stem cell research review, and conflict of interest review.

5.1.11.1. If the relying organization will have additional reviews conducted, the USM IRB will initiate its review subsequent to the conclusion of these reviews and after any determinations has been made.

5.1.11.2. If an additional review(s) has been conducted by an external organization, the USM IRB will request a copy from the relying organization of the determination(s) to upload into the e-Protocol system to be part of the USM IRB review.

5.1.11.3. The relying organization will inform the USM IRB of circumstances when the external review must take into account additional regulatory requirements, for example, those of the DoJ.

5.1.11.4. The USM IRB will also request documentation from the relying organization regarding education for researchers when using these additional reviews.

5.2. When USM relies on an External IRB

5.2.1. A USM PI may request that USM defer IRB review to another organization.

5.2.1.1. ORIO Staff determines whether to defer review on a case-by-case basis.

5.2.1.2. USM's HRPP will defer review of exempt activities or activities deemed to be not human subject research on a case-by-case basis.

5.2.2. The USM PI provides the ORIO with general information using the Request for Review of External IRB Approval form.

5.2.3. The USM IRB reviews authorization forms and/or waiver of authorization forms for our institution.

5.2.3.1. USM's IRB allows the external IRB to review authorization forms if the external IRB agrees to incorporate USM's authorization requirements in the combined consent/authorization form.

5.2.4. The USM PI complies with the reviewing IRB's policies and procedures for initial and continuing review, record keeping, and reporting requirements, and that all information requested by the reviewing IRB is provided in a timely manner.

5.2.5. To ensure that the external IRB obtains information necessary to make required determinations for unanticipated problems involving risks to participants or others, USM is responsible for:

5.2.5.1. Promptly informing the external IRB of any local context issues as requested by the external IRB;
5.2.5.2. Promptly reporting to the external IRB any serious or continuing noncompliance in connection with a study in accordance with the external IRB's reporting requirements;
5.2.5.3. Promptly reporting to the external IRB any unanticipated problems involving risks to participants or others in connection with a study in accordance with the external IRB's reporting requirements;
5.2.5.4. Promptly reporting protocol deviations and other events or issues in accordance with the external IRB's reporting requirements;
5.2.5.5. Maintaining a system for receiving and addressing subject complaints about the study and providing this information to the external IRB; and
5.2.5.6. Ensuring that investigators and research staff who are conducting the protocol are appropriately qualified and meet USM's standards for eligibility to conduct research

5.2.6. USM will conduct conflict of interest reviews prior to review by the external IRB pursuant *to HRPP-023 IRB Member and IRB Staff Conflict of Interest* and *HRPP-045 Financial Conflicts of Interest*.

5.2.6.1. When appropriate, USM will promptly communicate the results of this review to the external IRB in accordance with the external IRB's reporting requirements.

5.2.7. Investigators and research staff may contact the Regulatory Compliance Administrator to obtain answers to questions, express concerns, and convey suggestions when using an external IRB for review.

5.3. When USM relies on a Non-AAHRPP (Association for the Accreditation of Human Research Protections Program) Accredited External IRB:

5.3.1. USM may agree to defer responsibility for IRB review to a non-AAHRPP accredited institution's IRB for research that is not greater than minimal risk.

5.3.1.1. The relied upon IRB will provide the approval letter, original protocol, and all supporting documents, and reviewer communications with the investigator(s) to USM's Research Compliance Administrator in order to ensure it was reviewed appropriately and complies with applicable laws and regulations.

5.3.2. To defer responsibility, the non-USM IRB must have an OHRP-approved FWA and an OHRP-registered IRB.

5.3.3. Assurance of compliance with applicable laws and regulations must be documented through the completion of a written reliance agreement.

5.4. General Organizational Responsibilities

5.4.1. The USM IRB requires a written reliance agreement to be completed between organizations involved in a reliance relationship.

5.4.2. The written agreement describes which organization is responsible for the following:

5.4.2.1. Human subjects research education qualifications of investigators and research staff;
5.4.2.2. Scientific review;
5.4.2.3. Concordance between any applicable grant and the IRB application;
Review of potential non-compliance, including complaints, protocol deviations, and results of audits:
5.4.2.4.1. Identifying which organization is responsible for deciding whether each allegation of non-compliance has a basis in fact; and
5.4.2.4.2. Identifying which organization's process is used to decide whether each incident of non-compliance is serious or continuing;
5.4.2.5. Development of management plans for investigators and research staff when a conflict of interest exists;
5.4.2.5.1. The management plan must be provided to the IRB in a timely manner prior to the decision by the IRB.

5.4.2.6. Management of organizational conflict of interest related to the research; and continued oversight of active studies until closure or a mutually agreed upon transfer of the studies, should a reliance agreement be terminated.

5.5. Additional Responsibilities under DHHS or the U.S. Food and Drug Administration (FDA)

5.5.1. The USM IRB requires supplementary information be contained in a reliance agreement for research under DHHS or FDA purview.

5.5.1.1. Records must include documentation specifying the responsibilities that a relying organization and an organization operating an IRB each will undertake to ensure compliance with the requirements of the Common Rule.

5.5.2. In addition to the general organizational responsibilities, the written agreement must outline which organization is responsible for determining the following:

5.5.2.1. Whether the relying organization applies its FWA to some or all research and ensuring the IRB review is consistent with the relying organization's FWA;
5.5.2.2. Which organization is responsible for obtaining additional approvals, if necessary, from HHS when the research involves pregnant women, fetuses, and/or neonates, children, or prisoners; and
5.5.2.3. Which organization is responsible for reporting serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions or terminations of IRB approval.

5.6. Additional Responsibilities under NIH

5.6.1. The NIH requirement for sIRB review applies to awardees in the United States and participating research sites within the United States.

5.6.2. The USM IRB requires supplementary information be contained in a reliance agreement for non-exempt protocols that fall under the NIH requirement for sIRB review.

5.6.3. In addition to the general organizational responsibilities, the written agreement must outline which organization is responsible for determining the following:

5.6.3.1. Ensuring reliance agreements are in place and documentation is maintained;
5.6.3.2. Additional certification requirements such as the NIH Genomic Data Sharing Policy; and

5.6.3.3. Determining the reliance on a single IRB versus conducting local IRB review in accordance with NIH policy on exceptions from single IRB review.

5.6.4. At USM, the Regulatory Compliance Administrator is responsible for managing authorization agreements.

6.0 References

6.1. 21 CFR 50;

6.2. 21 CFR 56;

6.3. 45 CFR 46.114;

6.4. FDA Cooperative Research Guidance;

6.5. FDA Non-Local IRB Review Guidance;

6.6. OHRP Engagement Memo;

6.7. OHRP Terms of the Federalwide Assurance of Protection for Human Subjects