UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-021
AAHRPP:	Element I.1.E., Element II.1.A., Element II.1.B., Element II.1.E. & Standard I-9
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Procedure Title:	IRB Composition and Membership

1.0 Objective

1.1. To describe the policies and procedures in accordance with the University of Southern Maine's (USM) Institutional Review Board (IRB) composition and membership for the protection of human subject research that falls under the USM Human Research Protection Program (HRPP).

2.0 General Description

2.1. IRB membership and composition will be reflective of the regulatory requirements of 45 CFR 46.107.

2.2. IRB members shall have the knowledge, skills, and abilities necessary to carry out the function of the IRB.

2.3. The membership of the IRB(s) shall be qualified through experience and expertise, or the use of consultants, to review research.

3.0 Responsibility

3.1. Execution of this SOP: IRB Chair, Provost, HPA, ORIO Staff and IRB Members

4.0 IRB Membership

4.1. USM IRB(s) shall have at least five (5) members, USM IRB(s) will consist of at least nine (9) voting members with varying backgrounds that promote complete and adequate review of research conducted at USM.

4.2. The IRB(s) shall be composed of members sufficiently qualified through experience and expertise. In the selection of IRB members, consideration will be given to the diversity of its members, including race, gender, cultural backgrounds, and sensitivity to community attitudes. The IRB(s) will be composed of at least one member whose primary concerns are not scientific, at least one member whose primary concern is scientific and at least

one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution. Every nondiscriminatory effort will be made to ensure that the IRB is diverse and representative in its membership. The IRB(s) acknowledge that a single member may fulfill one or more of these requirements.

4.3. No IRB will consist entirely of men, or entirely of women.

4.4. The IRB(s) will include at least one member who represents the general perspectives of participants.

4.5. The IRB(s) will include membership from more than one profession or specialty. The IRB(s) will be composed of individuals possessing the professional competence to review research activities adequately and qualified to review the types of research brought before it for review. The IRB(s) will include members who are knowledgeable about and experienced working with subjects vulnerable to coercion or undue influence, regularly included in the research under review, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, and experienced in working with these categories of subjects.

4.6. The IRB(s) shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.

4.7. A member is considered affiliated if they or a member of their immediate family is a full or part-time employee of USM. A member is also considered affiliated if they or a member of their immediate family is affiliated with USM on a basis other than employment or appointment, such as consultant, student, retiree, or former employee. A member is considered not to be affiliated if they are not otherwise affiliated with USM and who are not part of the immediate family of a person who is affiliated with USM. (45 CFR 46.107(c).)

4.8. Alternate members may be appointed as needed for primary member(s). The appointment of alternate member(s) should be based on expertise similar to that of the primary member(s). If a primary member has an alternate, the rosters shall indicate such designation. An alternate member may vote at a convened IRB meeting only when the primary member is absent. Alternate members may be assigned as reviewers on research studies if the primary member is not able to conduct reviews or the alternate member is used for their expertise at a particular meeting or on a particular project. Alternate members may be assigned to review expedited research or make exempt determinations.

4.9. Other persons may be called upon for their expertise to consult for the IRB in reviews and analysis, but these persons may not vote unless they are formal members of the IRB.

4.10. The majority of all IRB meetings in a year must have a nurse member present and in voting status.

5.0 Appointments and Terms of Service

5.1. The composition of the IRB will be periodically evaluated and appropriate adjustments in membership and composition will be made by the Institutional Official (IO) or their designee.

5.2. At the discretion of the IO, ORIO Staff may be appointed as IRB members.

5.3. Members of the IRB(s), including alternates, are appointed by the USM IO. Nominations by individuals or programs within USM to the IO should include a description of the individual's qualifications.

5.4. Members shall be appointed for a period of one, two or three-year terms. New members will be allowed a one-year appointment but can accept a longer term if they so agree. All other members are requested to commit to either a two or three-year term after their first term or initial one-year appointment. This reduces the effect of turnover and ensures a consistent voting membership.

5.5. Reappointment terms can be for two or three years and must be by mutual consent of the member, the IRB Chairperson, and the IO. Reappointments are made by the IO. There is no limit to the number of terms an individual may serve, but it is suggested that a member serve two terms and then rotate terms with other individuals. If a member wishes to continue service, a recommendation is made to the IO for reappointment. An effort will be made to stagger IRB member appointments over three years so that only one-third of terms will expire each year.

5.6. The IO may remove a member from the IRB before the end of his/her appointed term. The IRB Chair in consultation with the IRB staff may submit a request for removal to the IO based on the member's failure to carry out the responsibilities of an IRB member (e.g., failure to attend meetings regularly, failure to comply with regulations and policies). The IO makes the final decision. Members may request to be removed from the IRB without providing a reason and will be removed with notification to the IO.

5.7. IRB members shall:

5.7.1. Uphold federal, state, country, and local regulations, institutional policies and procedures, and ethical standards for the protection of human research subjects.

5.7.2. Attend at least fifty-percent (50%) of IRB meetings and contribute to the discussion during meetings.

5.7.3. Review IRB meeting materials prior to the IRB meeting.

5.7.4. Perform a review of studies as assigned.

5.7.5. Act as a lead reviewer on full review studies as assigned, including:

5.7.5.1. Provide a written summary of review (including reviewer comments).
5.7.5.2. Present results of reviews at IRB meetings.

5.7.6. Maintain any special or required credentials for those serving in specialized roles.

5.7.7. Review studies applying current IRB policies and procedures.

5.7.8. Provide timely written or electronic feedback on all application materials assigned. Timeliness is based upon the deadline provided as part of the particular review assignment.

5.7.9. Disclose conflict(s) of interest pursuant to HRPP-023 IRB Member and IRB Staff Conflict of Interest.

5.7.10. Communicate with researchers as needed.

5.7.11. Communicate with their departments or partner institutions and provide updates concerning IRB activities.

5.7.12. Maintain confidentiality of IRB materials and information when information is private.

5.7.13. Participate in activities to enhance development as an IRB member, such as:

5.7.13.1. Fulfill all IRB educational requirements such as Collaborative Institutional Training Initiative (CITI) training or its equivalent every four (4) years;
5.7.13.2. Attendance of annual continuing education on human research activities;
5.7.13.3. Evaluation processes

5.7.14. Take an active part in the voting process when present for board meetings.

5.7.15. Recuse oneself from voting or participating in IRB business when the member has a clear or perceived conflict of interest concerning the matter at hand.

5.7.16. Recuse oneself from voting or participating in IRB business when the member is the topic of business, including when the member is the PI of a Full Board Review.

5.8. The IO shall appoint an IRB Chair and Vice-Chair for two-year terms. Reappointments are made by the IO with the consent of the IRB Chairperson. There is no limit to the number of terms an individual may serve as Chair or Vice-Chair. The Vice-Chair may be trained to replace the Chair in the future.

5.9. Responsibilities of the IRB Chair(s):

5.9.1. Uphold federal, country, and local regulations, USM policy and procedures, and ethical standards for the protection of human research subjects.

5.9.2. Provide leadership to the IRB.

5.9.3. Conduct noncompliance investigations with others, as necessary.

5.9.4. Review unanticipated problems involving risk to subjects or others and determine immediate actions.

5.9.5. Evaluate and mediate subject complaints and when needed, arrange for review by the IRB.

5.9.6. Act on the IRB's behalf, when appropriate, to suspend research pending IRB review of unanticipated problems involving risk to subjects or others and noncompliance.

5.9.7. Assist the IO and ORIO staff to ensure prompt reporting to the IRB, appropriate institutional officials (IO), Federal departments or agency heads, USM administrators, the U.S. Office for Human Research Protection (OHRP), the US Food and Drug Administration (FDA), and others, as required, of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with IRB policies or the requirements or determinations of the IRB, and any suspension or termination of IRB approval.

5.9.8. Consult with UMS System Counsel as needed (e.g., identification and interpretation of federal, country or local laws, during noncompliance investigations).

5.9.9. Mediate discussions between investigators and IRB members when needed.

5.9.10. Provide the RCA with guidance when asked to assist in the assignment of IRB members to review applications. Determine if a consultant is necessary to provide additional expertise.

5.9.11. Ensure conditions have been met for conditional approvals when appropriate.

5.9.12. Request emergency meetings or cancel meetings when necessary.

5.9.13. Chair IRB meetings.

5.9.14. Vote at the IRB meetings.

5.9.15. Maintain communications and relations with IRB members, the IO, USM administrators, and others, as needed.

5.9.16. Prepare Vice-chair(s) to assist the Chair and perform the Chair's duties when the Chair is not available.

5.9.17. Perform a review of studies as assigned.

5.9.18. Consult with UMS System Counsel or others for advice on conflict of interest. Identify and manage conflict of interest as needed.

5.9.19. Provide information for the evaluation of the IRB (e.g., membership, composition, recommendations) to the IO, as appropriate.

5.9.20. Participate in audits as appropriate.

5.9.21. Promote continuing education for IRB members.

5.9.22. Evaluate IRB members and provide recommendations for composition and appointment to the IO, as appropriate.

5.9.23. Recommend appointment of Vice-chairs to the IO, as appropriate.

5.9.24. Provide guidance to ORIO staff and the HPA on IRB study-related questions, concerns, or issues.

5.10. The IRB Vice-chair(s) shall:

5.10.1. Assist the Chair as necessary.

5.10.2. Perform the Chair's duties when the Chair is not available.

5.10.3. Perform other duties as assigned by the IO or Chair

6.0 IRB Roster:

6.1. The ORIO IRB will maintain the roster(s) of IRB members and alternate members. The roster(s) will be updated when changes are made.

6.1.1. The roster(s) shall include:

6.1.1.1. Names;
6.1.1.2. Earned degrees;
6.1.1.3. Representative capacities
6.1.1.4. Scientific/nonscientific status;

6.1.1.5. Affiliation status (whether the IRB member or an immediate family member of the IRB member is affiliated with the organization);
6.1.1.6. Indications of experience sufficient to describe each IRB member's chief anticipated contributions;
6.1.1.7. Employment or other relationship between each IRB member and the organization;
6.1.1.8. Alternate members;
6.1.1.9. The primary members or class of primary members for whom each alternate member can substitute;
6.1.1.10. Status (e.g., voting member, non-voting liaison, non-voting members voting/non-voting ex-official, etc.).

7.0 References:

7.1. 45 CFR § 46.107;

7.2. 45 CFR § 46.103(b)(3);

7.3. 45 CFR § 46.108(b);

7.4. OHRP step-by-step Instructions on Registering an Institutional Review Board (IRB) or Independent EC (IEC);

7.5. 21 CFR §56.108(a);

7.6. 21 CFR §56.115(a)(5);

7.7. 45 CFR § 46.304;

7.8. OHRP Guidance on written IRB Procedures;

7.9. 21 CFR §56.107;

7.10. FDA Information Sheets: Non-Local review, IRB Membership;

7.11. FDA Information Sheets: Frequently Asked Questions: IRB Membership;

7.12. FDA Information Sheets: Frequently Asked Questions: IRB Procedures