UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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| **Procedure #:** | HRPP-009 |
| **AAHRPP** | Element II.2.D. |
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| **Prepared By:** | Casey Webster, Research Compliance Administrator |
| **Reviewed By:** | IRB Chair; IRB; ORIO |
| **Procedure Title:** | Conduct of IRB Meetings |

## 1.0 Objective

**1.1**. To describe the policies and procedures for the preparation, scheduling, and conduct of convened meetings of the Institutional Review Board (IRB).

## 2.0 General Description

**2.1.** The University of Southern Maine (USM) IRB conducts convened meetings in accordance with applicable federal requirements for full review.

## 3.0 Responsibility

**3.1.** It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), IRB Chair, and IRB members to execute this Standard Operating Procedure (SOP).

## 4.0 Procedures

**4.1.** Scheduling of the Meeting

4.1.1. ORIO staff develop, maintain, and revise the IRB meeting schedule, as appropriate. The dates are available on the ORIO website or by request.

4.1.2. ORIO staff handle the meeting rooms and catering arrangements after confirming the meeting dates.

4.1.3. ORIO staff send an appointment notice to IRB members approximately fourteen (14) calendar days before a meeting.

4.1.4. In the event that the IRB requests a Principal Investigator's (PI) attendance at the meeting, ORIO staff send an appointment notice to the PI at least 2 calendar days before the meeting.

**4.2.** Preparation of the Agenda

4.2.1. ORIO staff create an agenda approximately ten (10) calendar days before a meeting.

4.2.2. The agenda serves as a guideline for the conduct of the meeting. The agenda may include additional items at the discretion of the IRB Chair, ORIO Staff, RCA, or IRB members.

4.2.3. The IRB Chair or designee reviews the agenda for accuracy and completeness before its distribution to the IRB.

**4.3.** Distribution of the Meeting Materials

4.3.1. ORIO staff send the agenda and other meeting materials to IRB members and any other appropriate individuals approximately seven (7) calendar days before the meeting.

4.3.2. Guests do not receive a copy of protocol material. Consultants receive protocol materials only for the particular protocol they are consulting on.

**4.4.** Quorum Requirements

4.4.1. A majority (e.g. IRB members = 11; majority = 6) of the IRB members must be present for quorum.

4.4.1.1. ORIO staff will notify the Chair when quorum is established and document member attendance throughout the convened meeting to ensure continued quorum.

4.4.2. IRB Members are required to attend fifty percent of meetings in a calendar year.

4.4.2.1 ORIO staff track IRB Member attendance.

4.4.3. When the convened IRB reviews any research project:

4.4.3.1. At least one member whose primary interests are in nonscientific areas must be present.
4.4.3.2. At least one member who is not affiliated with USM must be present.
4.4.3.3. At least one member who represents the general perspective of participants must be present.
4.4.3.4. At least one member whose primary interests are in scientific areas must be present.

4.4.4. When the convened IRB reviews Food and Drug Administration (FDA) regulated research, at least one member who is a licensed physician must be present.

4.4.5. When the convened IRB reviews research involving prisoners, at least one member who is a prisoner representative must be present.

4.4.6. When the convened IRB reviews nursing research, at least one member who is a nurse must be present.

4.4.7. When the convened IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, there must be at least one member or consultant who is knowledgeable about or experienced in working with such participants present. Otherwise, the review will be deferred until such expertise can be obtained.

4.4.8. Alternate members may attend any meeting; however, they may only vote in the place of their absent regular member in order to meet the quorum requirements.

4.4.9. The IRB does not consider consultants or other guests in establishing a quorum.

4.4.10. Members must excuse themselves from the meeting during a vote when they have a conflict of interest. In such cases, they do not count as a part of the members necessary to constitute a vote or majority. The Chair may ask the conflicted member to provide some information before recusing for final discussion and vote.

4.4.11. If the quorum is lost during a meeting (e.g., loss of a majority through excused members with conflicting interests or early departure or absence of a non-scientist member, etc.), the IRB does not take further protocol actions that require a vote unless the quorum is restored.

**4.5.** Review of Protocols

4.5.1. The IRB Chair, Vice Chair, or any voting IRB member may chair the convened meeting.

4.5.1.1. The duties of the Chair include, but are not limited to:

4.5.1.1.1. Preside over IRB meetings and ensure that meetings are conducted in an efficient, orderly and fair manner with respect given to the opinions of all members;

4.5.1.1.2. Ensure a quorum for each study review and ensure that this quorum is properly documented by ORIO staff;

4.5.1.1.3. Ensure that all regulatory-required elements of review are addressed during the meeting and that there is meaningful and substantive discussion of relevant matters and/or questions;

4.5.1.1.4. Ensure that assigned reviewers present a clear and concise review of study materials including consent documents and recruitment items and process;
4.5.1.1.5. Ensure that all IRB-required changes to consent and other documents are documented;
4.5.1.1.6. Accept appropriate motions from voting members of the IRB;
4.5.1.1.7. Ensure that the specific elements pertaining to any motions are clearly understood by the IRB and accurately recorded in the meeting minutes;
4.5.1.1.8. Ensure that IRB decisions are made in accordance with federal, state and local regulations and with the USM SOPs.
4.5.1.1.9. Review the minutes of IRB meetings and votes of the IRB members to ensure it accurately reflects discussions and actions.

4.5.2. For initial full review, the IRB may require that PIs attend the convened meeting. The IRB, IRB Chair, or ORIO staff may grant permission for the co-investigator or knowledgeable party to attend in place of the PI.

4.5.3. For other types of review, IRB members, the IRB Chair, or ORIO staff may also invite or require the PI to attend, when deemed appropriate.

4.5.4. To the extent possible, the proceedings of the meetings are confidential. Guests may be invited to attend or request to attend as observers.

4.5.4.1. Upon receipt of a request to observe, ORIO staff or the IRB Chair may grant permission for attendance by these individuals.
4.5.4.2. ORIO staff obtain a statement of confidentiality from guests who have permission to attend.

4.5.5. IRB members do not participate in the review of any component of a project in which the member has a conflict of interest, except to provide information requested by the IRB.

4.5.6. ORIO staff are responsible for preparing meeting minutes.

**4.6.** Telephone or Videoconference Participation

4.6.1. The IRB may conduct convened meetings by telephone or video conferencing as long as IRB member(s) have received a copy of all of the documents under review at the meeting, a quorum as defined above is present, and discussion occurs in real time.

4.6.1.1. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place.

4.6.1.2. Such members count as part of the quorum and may vote.
4.6.1.3. The IRB Chair will ask for a vote by name for each remote member.

**4.7.** Motions

4.7.1. Primary reviewers lead the discussion regarding the submission under review and are expected to propose a motion for the committee to vote upon, although any IRB member may propose a motion.

4.7.2. The range of motions available to IRB members are outlined below for specific review types below.

4.7.2.1. Initial Review Applications and Changes of Protocol
4.7.2.1.1. Approved as Submitted
4.7.2.1.1.1. No modifications or clarifications are being requested from the PI in order to secure final IRB approval.
4.7.2.1.2. Approved with Administrative Hold
4.7.2.1.2.1. All conditions for IRB approval have been met, but the IRB cannot approve the study as submitted until further documentation is in place. This motion is used in limited cases, such as ensuring the IRB receives documentation of final approval from other institutional committees or another site or when documentation of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) number has been requested but are not yet available.
4.7.2.1.3. Modifications Requested
4.7.2.1.3.1. A PI needs to make minor revisions to the IRB application or supporting materials that can be reviewed under expedited procedures to secure IRB approval. Or the committee can specify the revisions to the IRB application such that the response can be reviewed by the RCA for concurrence with the IRB's requests.
4.7.2.1.4. Deferred
4.7.2.1.4.1. If the IRB cannot determine that a study meets ALL of the criteria for IRB approval under the federal regulations and cannot specify the revisions that would allow the study to be approved under these regulations, then the IRB is required to defer review of the submission. Please note that revisions to consent documents must be minor or specific in order to allow the

IRB to request modifications rather than deferring the study. If the IRB is requesting clarifications from a PI rather than specific revisions, a motion for deferral is generally appropriate.

4.7.2.2. Unanticipated Problems
- 4.7.2.2.1. Acknowledge report: not an unanticipated problem
  - 4.7.2.2.1.1. The IRB has determined that the report does not meet the institutional definition of an unanticipated problem.
- 4.7.2.2.2. Acknowledge report: unanticipated problem and no additional action required to resolve the report
  - 4.7.2.2.2.1. The IRB determines that the report meets the institutional definition of an unanticipated problem and the plan for preventing similar occurrences and/or informing subjects is sufficient.
- 4.7.2.2.3. Defer: report does not constitute an unanticipated problem, but additional action needed to resolve the report
  - 4.7.2.2.3.1. The IRB determined that the report does not meet the institutional definition of an unanticipated problem but additional information or action on the part of the PI is needed to address issues or questions raised by the report.
- 4.7.2.2.4. Defer: additional information needed to determine whether report constitutes an unanticipated problem
  - 4.7.2.2.4.1. The IRB does not think it has sufficient information to determine whether the report meets the institutional definition of an unanticipated problem.
- 4.7.2.2.5. Defer: report constitutes an unanticipated problem and additional action required to resolve the report
  - 4.7.2.2.5.1. The IRB determines that the report meets the institutional definition of an unanticipated problem and the plan for preventing similar occurrences and/or informing subjects is not sufficient.

4.7.2.3. Noncompliance
- 4.7.2.3.1. Acknowledge: not serious or continuing noncompliance and no additional action required
  - 4.7.2.3.1.1. The IRB determines that the report does not meet the institutional definition of noncompliance and no additional information or

action is needed from the PI to resolve the report.

4.7.2.3.2. Defer: not serious or continuing noncompliance but additional action required

4.7.2.3.2.1. The IRB determines that the report does not meet the institutional definition of noncompliance, but additional information or action is needed from the PI to resolve the report.

4.7.2.3.3. Defer: a determination related to the report cannot be made

4.7.2.3.3.1. The IRB does not think it has sufficient information to determine if the report meets the institutional definition of noncompliance, or institutional definition of serious and/or continuing noncompliance.

4.7.2.3.4. Defer: preliminary determination of serious and/or continuing noncompliance

4.7.2.3.4.1. The IRB preliminarily determines that the event appears to meet the institutional definition of serious and/or continuing noncompliance. The IRB should specify whether additional action is needed on the part of the PI to prevent similar noncompliance from occurring in the future and whether any notification to research subjects related to the noncompliance is necessary. The PI will then have an opportunity to respond to the IRB's requests and the committee will review the response to determine if the preliminary finding of serious and/or continuing noncompliance stands.

4.7.2.3.5. Acknowledge: final determination of serious and/or continuing noncompliance and no additional study team action needed

4.7.2.3.5.1. The IRB reviews a PI's response to determine if the preliminary finding of serious and/or continuing noncompliance stands. If a final determination of serious and/or continuing noncompliance is made, the IRB must specify whether the noncompliance requires reporting to an external agency, such as the study sponsor, Office for Human Research Protection (OHRP) or the FDA.

4.7.2.3.6. Defer: final determination of serious and/or continuing noncompliance - additional information or action needed

4.7.2.3.6.1. The IRB reviews a PI's response and determines that the response requires additional information

or action in order to resolve, which would require a deferral.

**4.8.** Voting

4.8.1. IRB members may not vote by email or by proxy. However, members can provide written comments for IRB consideration.

4.8.2. Voting is conducted by raising hands (and voice vote by members participating by teleconference).

4.8.2.1. Votes are counted by ORIO staff and confirmed by the Chair.

4.8.3. Voting may be conducted anonymously on paper, if requested by a member or deemed appropriate by the Chair.

4.8.4. Voting at a convened meeting takes place under the following conditions:

4.8.4.1. A majority of the IRB members must be present (or connected via speakerphone/video) for all reviews/actions voted on at a convened meeting;
4.8.4.2. A passing vote must consist of a majority of members present (or connected via speakerphone/video) voting in favor of the motion;
4.8.4.3. An individual who is not listed on the IRB membership roster may not vote with the IRB;
4.8.4.4. Guests and consultants may not participate in the vote;
4.8.4.5. A non-scientist member must always be present for a vote;
4.8.4.6. A physician must be present to vote on FDA regulated research;

## 5.0 References

**5.1.** 21 CFR 56.108(c);

**5.2.** 21 CFR 56.109;

**5.3.** 45 CFR 46.108(b);

**5.4.** 45 CFR 46.103(b)(3);

**5.5.** OHRP step-by-step instruction registering an Institutional Review Board (IRB) or Independent EC (IEC);

**5.6.** 21 CFR 56.115(a)(5);

**5.7.** FDA Information Sheets: Frequently Asked Questions: IRB Membership;

**5.8.** FDA Information Sheets: Frequently Asked Questions: IRB Procedures