UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-019
AAHRPP:	Element II.1.D., Element II.2.D. & Element II.5.B.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	IRB Minutes

1.0 Objective

1.1. To describe policies and procedures for completing the minutes of convened meetings of the Institutional Review Board (IRB).

2.0 General Description

2.1. The federal policies for the protection of human subjects require that minutes of IRB meetings be in sufficient detail to show:

2.1.1. Attendance at the meeting;

2.1.2. Actions taken by the IRB;

2.1.3. The vote on these actions including the number of members voting for, against, and abstaining;

2.1.4. The basis for requiring changes in or disapproving research; and

2.1.5. A written summary of the discussion of controverted issues and their resolution.

2.2. Good minutes enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions.

2.2.1. They also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

2.3. Meeting minutes do not have to contain information provided in protocols the IRB has previously approved.

2.3.1. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable.

3.0 Responsibility

3.1. 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.

4.0 Procedure

4.1. Minutes Preparation

4.1.1. The ORIO staff member attending the convened IRB meeting drafts detailed notes to document IRB discussions and determinations.

4.1.2. ORIO staff use the IRB minutes template as a guide in drafting minutes.

4.1.3. Examples of the type of information included in the minutes are as follows:

4.1.3.1. The location of the meeting;
4.1.3.2. The time the IRB convened the meeting and adjourned;
4.1.3.3. Documentation of attendance to include:
4.1.3.3.1. Each member's full name;
4.1.3.3.2. Each member's representative capacity (scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated);
4.1.3.3.3. The names of members who participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing;
4.1.3.3.4. If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB on the study;
4.1.3.3.5. The names of non-members and guests, such as IRB support staff, researchers, and study coordinators;
4.1.3.3.6. Initial and continued presence of a majority of members (i.e., quorum), including at least one nonscientist;
4.1.3.3.7. Whether an alternate is voting and for whom he or she is voting;
4.1.3.3.8. When a member leaves the room or leaves the meeting;
4.1.3.3.9. That a licensed nurse was present for review of nursing protocols; and
4.1.3.3.10. That a licensed physician was present for review of all FDA protocols.

4.1.3.4. Minutes on the review of each protocol to include the following:

4.1.3.4.1. The names of IRB members excused from the meeting due to a conflict of interest during the discussion and vote of the study;

4.1.3.4.1.1. IRB members with a conflict are documented in the minutes as being absent with an indication that a conflict of interest was the reason for the absence.

4.1.3.4.1.2. The minutes reflect that IRB members with a conflict of interest do not count towards quorum for the review.

4.1.3.4.2. Separate deliberations for each action taken by the IRB;

4.1.3.4.3. A summary of the discussion of any controverted issues and their resolutions;

4.1.3.4.4. The vote on these actions, including the number of voting "for," "opposed," or "abstaining";

4.1.3.4.4.1. In order to document the continued existence of a quorum, ORIO staff record votes in the minutes using the following format: VOTE: For = 14, Opposed = 0, Abstained = 1;

4.1.3.4.5. The IRB's determination on frequency of continuation review (based on the degree of risk or the risk/benefit ratio);

4.1.3.4.6. Name of the investigator and others attending the meeting;

4.1.3.4.7. The basis for requiring changes in the research;

4.1.3.4.8. The level of risk determined by the IRB at initial review

4.1.3.4.8.1. On all other reviews, the minutes only list level of risk if it has changed.

4.1.3.5. Motions of the IRB, recorded in their entirety, including exact wording of any conditions of approval;

4.1.3.6. Determinations made by the convened IRB related to the review of non-compliance, protocol deviations, unanticipated problems involving risks to participants or others, serious adverse events, suspensions and terminations, and complaints;

4.1.3.7. Determinations made by the convened IRB when those determinations are required by other applicable federal requirements; and

4.1.3.8. Discussion of statements of any significant new findings provided by the investigator.

4.1.4. When the IRB disapproves a protocol, ORIO staff document the basis for the disapproval in the minutes and document discussion of the controverted issues.

4.1.5. ORIO staff write IRB meeting minutes impersonally and do not attribute opinions expressed by IRB members.

4.1.5.1. Typically, the minutes only identify members by name when they provide continuing education, are the subject of an announcement,

recuse themselves from a particular review due to conflict of interest, or leave the meeting for any reason.

4.1.6. In cases where a consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

4.2. Alternates

4.2.1. IRB meeting minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.

4.2.2. When alternates substitute for a primary member, the alternate member receives and reviews the same material that the primary reviewer received or would have received.

4.3. Specific Findings

4.3.1. When the IRB makes specific findings at convened meetings, ORIO staff document these findings in the minutes of the meeting and include protocol-specific information justifying each finding.

4.3.2. Examples of specific findings include, but are not limited to:

4.3.2.1. Alteration or Waiver of the Informed Consent Process in Non-FDA Requested Research:

4.3.2.1.1. When the convened IRB reviews a procedure that alters or waives the requirements of informed consent, the minutes document the IRB's determinations required by the federal regulations (45 CFR 46.116).

4.3.2.2. Waiver of Documentation of Informed Consent:

4.3.2.2.1. When the convened IRB reviews a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.117, 21 CFR 56.109).

4.3.2.3. Research Involving Deception:

4.3.2.3.1. When the convened IRB reviews research involving deception, the minutes document that the IRB made the findings in accordance with 45 CFR 46.116.

4.3.2.4. Research Involving Prisoners:

4.3.2.4.1. When the IRB reviews research involving prisoners, the minutes indicate that the research meets the findings required by 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by HHS 45 CFR 46.306(a).

4.3.2.4.2. At least one member of the IRB is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

4.3.2.4.3. In cases where more than one IRB reviews a particular research project, only one IRB need satisfy this requirement.

4.3.2.5. Research Involving Children:

4.3.2.5.1. When the IRB reviews research involving children, the minutes document that the IRB made the findings in accordance with IRB policy and federal regulations (HHS 45 CFR 46 Subpart D 46.404-46.407 and FDA 21 CFR Subpart D 50.50-50.55).

4.3.2.6. Wards of the State or Other Agency:

4.3.2.6.1. When the IRB reviews research involving children who are wards of the state or any other agency, institution, or entity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.409 and 21 CFR 50.56).

4.3.2.7. Research Involving Pregnant Women, Human Fetuses and Neonates:

4.3.2.7.1. When the IRB reviews research involving pregnant women, human fetuses, and neonates, the minutes must document that the IRB made the findings in accordance with federal regulations (45 CFR 46 Subpart B).

4.3.2.8. Research Involving Individuals with Impaired Consent Capacity:

4.3.2.8.1. When the IRB reviews research involving individuals who are determined to be cognitively impaired and/or lack consent capacity, the minutes document that the IRB made the findings in accordance with federal regulations [45 CFR 46.111(b), 21 CFR 56.111(b)], and local policy.

4.3.2.9. Investigational New Devices:

4.3.2.9.1. The minutes document the IRB's determination of significant or nonsignificant risk for Investigational New Devices and the rationale for that decision, in accordance with federal regulations [(21 CFR 812.3(m)].

4.4. Teleconference and Videoconference Participation

4.4.1. At a meeting in which IRB members participate via telephone or videoconference, meeting minutes document that the IRB member:

4.4.1.1. Has received all pertinent material prior to the meeting; and

4.4.1.2. Can actively and equally participate in the discussion of all protocols.

4.5. Distribution of Minutes

4.5.1. ORIO staff complete a draft of the IRB meeting minutes according to the IRB minutes template.

4.5.2. Draft minutes of IRB meetings are to be written and available for review no later than four (4) weeks after the date of the IRB meeting.

4.5.3. ORIO staff disseminate the draft minutes as part of the IRB agenda for the meeting at which the draft minutes are scheduled to be approved.

4.5.4. Each IRB member present during the convened meeting reviews the draft minutes and forwards any necessary revisions to the appropriate ORIO staff member.

4.5.4.1. The IRB delegates to ORIO staff the authority to correct administrative errors in meeting minutes as appropriate.

4.5.5. The IRB approves the minutes at the convened meeting.

4.5.6. ORIO staff distribute copies of approved minutes, as appropriate, when requested.

4.6. Record Keeping

4.6.1. ORIO staff maintain electronic copies of all minutes.

4.6.2. ORIO staff maintain copies indefinitely.

4.6.3. Records maintained that document compliance or non-compliance with U.S. Department of Defense (DoD) regulations shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

5.0 References

5.1. 45CFR 46.107;
5.2. 45 CFR 46.108;
5.3. 45 CFR 46.111;
5.4. 45 CFR 46.115 (a)(2);
5.5. 45 CFR 46.116;
5.6. 45 CFR 46.117;
5.7. 45 CFR 46.409;
5.8. 21 CFR 812.3(m);
5.9. 21 CFR 50.23;
5.10. 21 CFR 50.24;
5.11. 21 CFR 50.56