UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-025
AAHRPP:	Element II.1.E., Element II.2.D., Element II.2.E.1., Element II.2.E.2, Element II.2.E.3., Element II.3.A., Element II.4.A., Element II.5.B., Element III.1.B., Element III.1.C.
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Procedure Title:	Initial and Continuing Review at IRB Meetings

1.0 Objective

1.1 To describe policies and procedures for the conduct of IRB meetings to include initial and continuing review.

2.0 General Description

2.1. The IRB meeting will be conducted by the IRB Chair with administrative assistance from ORIO Staff. There are certain actions which are required by the 45 CFR 46 to include within the IRB meeting. There are also actions that are required when specific scenarios are present.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Human Protections Administrator (HPA), Institutional Review Board (IRB), and investigators to execute this SOP.

4.0 Procedure

4.1. The ORIO Staff will ensure that a quorum is present, including any required members (e.g., non-scientific member, non-affiliated member, representative for vulnerable populations). A majority of the IRB (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRB. ORIO Staff will record when any IRB Member leaves the room and return and record who is in the room when any vote is taken to ensure a quorum is present. When an IRB Member leaves the room due to a conflict of interest, the minutes will reflect that the Member left due to a conflict.

4.1.1. ORIO staff documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements and organizational policies and procedures.

4.2. The IRB Chair will call the meeting to order.

4.3. The IRB Chair will ask if any IRB Members have a conflict of interest for any of the research under review at the meeting. Conflicts will be noted accordingly.

4.4. An education program will be a component of the IRB meeting which will last at least 10 to 15 minutes.

4.5. Evaluation of research undergoing <u>initial</u> IRB review will be completed.

4.5.1. All board members receive a completed IRB application prior to the meeting, which includes the following:

4.5.1.1. Personnel information
4.5.1.1.1. Potential Conflict of Interest
4.5.1.1.2. Proof of Human Subject Research Training
4.5.1.1.3. Resume/CV
4.5.1.2. Study location
4.5.1.3. Funding
4.5.1.4. Purpose
4.5.1.5. Study procedures
4.5.1.6. Background
4.5.1.7. Provisions to monitor data if applicable
4.5.1.8. Investigator experience
4.5.1.9. Subject population
4.5.1.10. Subject compensation and costs
4.5.1.11. Recruitment
4.5.1.12. Potential benefits to participants
4.5.1.13. Risks
4.5.1.14. Provisions to maintain the confidentiality of data
4.5.1.15. Provisions to protect the privacy interests of participants
4.5.1.16. Informed consent or broad consent if appropriate
4.5.1.17. Informed assent
4.5.1.18. HIPAA
4.5.1.19. Attachments

4.5.1. Presentation by the primary and secondary reviewer;

4.5.2. Questions will be posed to the primary and secondary reviewer;

4.5.3. Discussion of whether the consent form is acceptable, identifying and analyzing risks, or if modifications are needed;

4.5.4. Discussion and resolution of controverted issues;

4.5.5. IRB will make protocol-specific determinations (e.g. waivers, subparts);

4.5.6. IRB Chair ensures criteria for approval of research have been satisfied;

4.5.7. Presentation of a motion;

4.5.8. IRB Members move and second the motion;

4.5.9. ORIO Staff records and reads the motion verbatim, including exact wording of any condition;

4.5.10. Discussion of motion, as necessary;

4.5.11. IRB Chair takes a vote

4.5.12. Determination of the approval period and expiration date.

4.6. Evaluation of research undergoing continuing review will be completed.

4.6.1. Presentation by the primary reviewer and follow-up questions;

4.6.2. Discussion of any changes in risk, identifying and analyzing change in risks, or if modifications are needed;

4.6.3. Discussion whether the consent form is still accurate and complete or if modifications are needed;

4.6.4. Discussion of any issues involved in the continuing review application;

4.6.5. IRB Chair ensures criteria for approval of research have been satisfied;

4.6.6. Presentation of a motion;

4.6.7. IRB members move and second the motion;

4.6.8. ORIO Staff records and reads the motion verbatim, including exact wording of any conditions;

4.6.9. Further discussion of motion, as necessary;

4.6.10. IRB Chair takes a vote;

4.6.11. Determination of the approval period and expiration date.

4.7. Review of amendments to previously approved research

4.7.1. Presentation by the primary reviewer and follow-up questions;

4.7.2. Discussion whether the amendments cause changes in risk, identifying and analyzing change, or if modifications are needed;

4.7.3. Discussion whether modifications to the informed consent are required;

4.7.4. Discussion of any issues observed in the amendment;

4.7.5. IRB Chair ensures that any relevant criteria for approval of research have been satisfied;

4.7.6. Presentation of a motion;

4.7.7. IRB Members move and second the motion;

4.7.8. ORIO Staff records and reads the motion verbatim;

4.7.9. Further discussion of motion, as necessary;

4.7.10. IRB Chair takes a vote.

4.8. If there is not at least one person at the IRB meeting with appropriate scientific or scholarly expertise to conduct an in-depth review of the protocol, the IRB will defer review until such expertise is obtained.

4.9. Any other business

4.9.1. IRB Chair will discuss any other business that may be on the Agenda, including but not limited to, unanticipated problems, and ask the IRB Members if there is any other business someone would like to discuss.

4.10. Adjournment

4.10.1. IRB Chair will adjourn the meeting.

5.0 Unanticipated Problems

5.1. Determine if there was an event;

5.2. Decision whether the event is an unanticipated problem involving risks to participants or others;

5.3. If an unanticipated problem does involve risk to participants or others, the IRB will acknowledge that the issue will be reported to appropriate Federal agencies, if required.

6.0 Non-Compliance

6.1. Review of any cases of non-compliance;

6.2. Decision whether non-compliance is serious or continuing;

6.3. If it is determined that non-compliance is serious or continuing, acknowledge that the non-compliance will be reported to the Institutional Officer (IO) and any appropriate Federal agencies or sponsors, if required.

7.0 Review and Documentation of Waivers of Certain Vulnerable Populations

7.1. Additional criteria must be met and documentation must be maintained if the research involves a vulnerable population such as:

7.1.1. Children;

7.1.2. Individuals with impaired decision-making capacity;

7.1.3. Economically or educationally disadvantaged persons;

7.1.4. Prisoners.

7.2. Additional criteria must be met and documentation must be maintained if the research involves any of the following requests:

7.2.1. Waiver or alteration of consent procedure;

7.2.2. Waiver of documentation; or

7.2.3. Alteration to, or waiver, in whole or in part, of the individual authorization required for use or disclosure of protected health information.

7.3. To determine whether the criteria have been met, the convened IRB shall review the researcher's explanation of why the request for a waiver or alteration of documentation is appropriate, and the submitted application. The investigator may be asked to explain and provide rationale for why each criterion is met for the waiver or alteration.

7.4. If the applicable criteria have been satisfied to approve the waiver or alteration of documentation, the details of the approval will be recorded in the minutes of the convened IRB meeting. A standard form shall be used for documentation and placed in the IRB file.

7.5. For applicable criteria, *see HRPP 029 Informed Consent*

8.0 Other IRB Decisions and Responsibilities

8.1. The IRB has the authority to observe, or have a third party observe, the informed consent process when the IRB determines it to be appropriate. The IRB determines which project needs verification, from sources other than the investigators that no substantive modifications have occurred since previous IRB review.

8.2. The IRB ensures, through education, applications and direct communications that investigators promptly report to the IRB proposed changes in a research activity including amendments to the protocol or the informed consent form and ensures that such changes in approved research are not initiated without IRB's review and approval, except when necessary to eliminate apparent immediate hazard to the subject.

9.0 Actions by the Convened IRB and Communication of Decisions

9.1. Approval will be granted when a majority of members present vote for approval at a convened meeting. The Institutional Official (IO) is responsible for further approval or disapproval of research that is approved by the IRB. The Chair and Vice-Chair may vote on all motions and each of their votes count equally toward any majority that is or is not reached. A majority of members present may also vote for tabling, conditional approval or disapproval of research studies. The communication of actions taken by the IRB will depend upon the action taken. Typically, the IRB administrator or IRB staff assists the IRB Chair or Vice-Chair in drafting the communication.

9.1.1. Tabling: Tabling occurs when the IRB defers the project for further review at a future date in order to obtain further information, modifications or clarification from the PI that would allow it to make a determination of approval according to 45 CFR 46.111 as appropriate. These may include situations that require substantive clarifications or modifications regarding the research study or the informed consent form(s) that are directly relevant to the determinations.

9.1.2. Conditional Approval: Conditional approval may be granted by the IRB when additional specific "minor" changes requiring simple concurrence by the investigator are needed. A letter from the IRB Chair or Vice-Chair will be sent to the researcher, if applicable, with the specific conditions that must be met for approval. The investigator needs to address the comments and submit his/her response to the IRB office in writing. The IRB Chair or designee will be given the discretion to accept those changes and determine that the conditions are met, or bring the research study back to the IRB for review. If the IRB Chair or designee accepts the changes and determines the conditions are met, an approval letter with approved consent form(s), if applicable, will be made available to the researchers typically through email. The approval date is the date the convened IRB approved the research study. However, research may not begin until the conditions are met and accepted by the IRB Chair or designee and the approval letter is sent to and received by the investigator(s). The IRB documents in the IRB minutes the date conditions were met, the date when initial approval becomes effective, and the expiration date.

9.1.2.1. Minor Conditions: A minor modification is one in which the IRB requests that the investigator makes specified changes to the research or submits clarification or additional documents, and once those minor conditions are satisfied, the IRB considers the criteria for approval satisfied. Modifications are considered minor if they will not change the risk to the participant regardless of the response. If the condition is prescriptive or confirmatory, it is usually minor. Minor conditions can be approved by the IRB Chair or designee. Responses to minor conditions do not need to return to the convened IRB for approval.

9.1.2.1.1. OHRP provides the following examples of minor conditions:

9.1.2.1.1.1. Confirm that the research excludes children.

9.1.2.1.1.2. Submit certificates confirming ethics training.

9.1.2.1.1.3. Precise language changes to informed consent documents (e.g., change "myocardial infarction" to "heart attack").

9.1.2.1.1.4. Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy (for example, add the method of screening for pregnancy).

9.1.2.2. Substantive Conditions: OHRP defines a substantive modification as one that is directly related to the determinations required for approval at the HHS regulations at 45 CFR 46.111 and, if applicable Subparts B, C and D. In other words, if you need the response to the condition to make a required regulatory determination, the condition is not minor, as the convened IRB is required to ensure that the regulatory criteria are satisfied. Usually if the condition requires a narrative response or involves an open-ended question and interpretation of whether it is met or not, it is probably not minor. The response to substantive conditions must be returned to the convened IRB for approval. Here are examples ORHP provides as substantive modifications:

9.1.2.2.1. Provide a justification for using a placebo and withholding currently available treatment for a serious medical condition for subjects assigned to a control group (this would be related to 45 CFR 46.111(a)(1) and (2)).

9.1.2.2.2. Revise the study hypothesis and, accordingly, the study design (related to 45 CFR 46.111(a)(1), (2), and (4)).

9.1.2.2.3. Describe the procedures that the control group will undergo (related to 45 CFR 46.111(a)(1), (2), and (4)).

9.2. Approval may be granted if the IRB determines that appropriate approval criteria have been met. The approval date is the date the majority of the convened IRB voted to

approve the research study. The approval letter(s) from the IRB Chair or Vice Chair and IRB approved consent form(s) if applicable will be made available to the researchers typically by email. A notification will be sent to the researchers via email instructing them to print the approval letter(s) and consent form(s) if applicable.

9.2.1. For initial review, the IRB may approve some components of the research for which the criteria of approval were satisfied, and defer approval of other components which require minor or substantive changes.

9.3. Disapproval: The IRB may disapprove of a research study. If a research study is disapproved, the investigator will be notified in writing. A letter from the IRB Chair or Vice-Chair will be sent to the researchers and will include a statement of the reasons for the IRB's decision. The letter will inform the investigator of his/her opportunity to appeal the decision in writing within 30 days. The written request to appeal the decision should clearly address the reasons provided for the IRB's decision, indicating the facts or the interpretation in dispute, providing supporting evidence where applicable. Within the response, the investigator notifies the IRB if they would like to present their appeal in person (including via teleconference or similar means) to the IRB. If the investigator would like to present their appeal to the IRB in person, the investigator may appeal the decision in person at the next IRB meeting.

9.3.1. If the investigator responds only in writing, the appeal will be discussed at the next IRB meeting. The IRB determines whether to change the disapproval determination after the appeal. The range of actions may include disapproval, approval, or request for modifications to obtain approval. The determination will be communicated in writing to the investigator.

10.0 Typical Review Times

10.1. Initial Applications: 4-6 weeks

10.2. Revisions: 2-4 weeks

10.3. Renewals: 3-6 weeks

11.0 Further Institutional Review

11.1. Further institutional review is applicable to research approved by the convened IRB in the same way as expedited approvals. See HRPP 018 IBC Coordination.

12.0 References:

12.1. 45 CFR 46.107;
12.2. 45 CFR 46.108;
12.3. 45 CFR 46.109;
12.4. 45 CFR 46.110;

12.5. 45 CFR 46.111;
12.6. 45 CFR 46.115 (a)(2);
12.7. 45 CFR 46.116;
12.8. 45 CFR 46.117;
12.9. 45 CFR 46.401;
12.9. 45 CFR 46.403;
12.10. 45 CFR 46.405;
12.11. 45 CFR 46.409;
12.12. 21 CFR 50;
12.13. 21 CFR 56.101;
12.14. 21 CFR 56.103;
12.15. 21 CFR 56.109;
12.16. 21 CFR 56.110;
12.17. 21 CFR 56.111;
12.18. 21 CFR 56.112;
12.19. HHS.gov *Draft Guidance on IRB Approval of Research with Conditions*, Section D https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/daft-guidance-irb-approval/index.html