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1. PURPOSE

- 1.1. This procedure establishes the process to conduct an IRB meeting.
- 1.2. This procedure begins when the meeting is called to order.
- 1.3. This procedure ends when the meeting is adjourned.

2. POLICY

- 2.1. The <Meeting Chair> is responsible to:
 - 2.1.1. Lead the IRB meeting
 - 2.1.2. Facilitate IRB review
 - 2.1.3. Ensure this SOP is followed
 - 2.1.4. Monitor the IRB's decisions for consistency
 - 2.1.5. Ensure that IRB members are free to participate in discussions
 - 2.1.6. Ensure that IRB members attending by teleconference can actively and equally participate in all discussions
 - 2.1.7. Vote as an IRB member
- 2.2. The <Meeting Chair> is expected to:
 - 2.2.1. Help IRB members meet their expectations in "POLICY: IRB Member Review Expectations (HRP-020)."
 - 2.2.2. Encourage IRB members to:
 - 2.2.2.1. Ask questions.
 - 2.2.2.2. Speak their minds at every protocol review
 - 2.2.2.3. Share information that has not been discussed.
 - 2.2.2.4. Listen and learn from the group.
 - 2.2.2.5. Respect dissenting opinions.
 - 2.2.2.6. Think and vote independently.
 - 2.2.3. Mentor and guide IRB members to use the criteria for approval by:
 - 2.2.3.1. Facilitating IRB members' understanding of the research to the degree sufficient to apply the criteria for approval.
 - 2.2.3.2. Having IRB members base concerns, problems, and recommended changes on the criteria for approval.
 - 2.2.3.3. Removing issues from consideration when the <Meeting Chair> and IRB members determine they do not affect the criteria for approval.
 - 2.2.3.4. Obtaining assistance when the <Meeting Chair> and IRB members are uncertain whether an issue affects the criteria for approval.
 - 2.2.3.5. Framing difficult or controverted issues in terms of the criterion that is the basis of the controversy.
 - 2.2.3.6. Taking votes on the criterion for approval that is the basis for a controversy, if after sufficient discussion a controverted issue remains unresolved,
 - 2.2.3.7. Reminding IRB members who believe that one or more criteria for approval voted are not met that they should not vote for approval.
 - 2.2.3.8. Supporting and rewarding dissent based on the criteria for approval
 - 2.2.4. Encourage IRB member engagement by:
 - 2.2.4.1. Reinforcing IRB member expectations
 - 2.2.4.2. Encouraging IRB members to use their unique perspective to contribute to IRB deliberations.
 - 2.2.4.3. Providing recognition and praise to IRB members.
 - 2.2.4.4. Caring about each IRB member as a person.
 - 2.2.4.5. Encouraging IRB members to develop in their review skills.

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- 2.2.4.6. Ensuring opinions of IRB members count.
- 2.2.4.7. Communicating the mission of the Temple IRB to protect subjects.
- 2.3. IRB members are to know the definition of <Conflicting Interest> and self-identify their <Conflicting Interests>.
- 2.4. The <Meeting Chair> may determine that certain IRB members have voting status and others have non-voting status.
 - 2.4.1. The number of IRB members with voting status is not greater than the number of regular IRB members on the IRB roster.
 - 2.4.2. During the meeting the <Meeting Chair> may change who has voting status and who has non-voting status.
 - 2.4.3. The <Meeting Chair> is responsible to notify the HRPP staff at the meeting of any change in IRB members' voting status.
- 2.5. All IRB members who are part of quorum may vote, including any IRB chairs, IRB vice-chairs, and <Meeting Chairs>.
- 2.6. Ad hoc substitutes may not serve as IRB members.
- 2.7. Absent IRB members may submit written comments, but may not vote.
- 2.8. Consultants may not vote.
- 2.9. Observers may attend meetings, but:
 - 2.9.1. May not participate in IRB deliberations unless requested by the IRB to serve as a consultant
 - 2.9.2. May not vote
 - 2.9.3. Must agree to maintain the confidentiality of the IRB proceedings
- 2.1. When a protocol is ambiguous, the IRB may resolve the ambiguity by obtaining written information from the sponsor or investigator in advance of the meeting as an alternative to contingent approval, IRB members must be made aware of this information, either orally or in writing.

3. RESPONSIBILITY

- 3.1. <Meeting Chairs> carry out these procedures.

4. PROCEDURE

- 4.1. Call the meeting to order.
- 4.2. Ask whether anyone has a <Conflicting Interest> related to any agenda item.
- 4.3. For each study review:
 - 4.3.1. If there are individuals (either IRB members or consultants) with a <Conflicting Interest> related to an agenda item:
 - 4.3.1.1. IRB members may ask questions of those individuals.
 - 4.3.1.2. If physically present, ask those individuals to leave the room.
 - 4.3.1.3. If present by teleconference, set the conference equipment to block communications or ask the member to leave the call during the review.
 - 4.3.2. If the study is eligible for <Non-committee Review>, the IRB can take no action and have the item reviewed by <Non-committee Review>.
 - 4.3.3. Take no action on the item when notified by an HRPP staff member that quorum requirements are not met¹ or when there is insufficient time.

¹ If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.

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- 4.3.3.1. Move the item to another meeting.
- 4.3.4. If one or more consultants are involved:
 - 4.3.4.1. Inform the IRB members of any <Conflicting Interest>.
 - 4.3.4.2. Have those present at the meetings discuss their findings.
- 4.3.5. Have the primary presenter:
 - 4.3.5.1. Have the individual(s) with scientific/scholarly expertise discuss the scientific/scholarly review.
 - 4.3.5.2. Review relevant findings of <Regulatory Review> and <Regulatory Review> contingencies.
 - 4.3.5.3. For a review related to an <Unanticipated Problem Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval> have the IRB determine whether any of these apply, unless already decided by the [Chief Research Compliance Officer], and if so, lead the IRB members through a discussion of "WORKSHEET: New Information (HRP-411)."
 - 4.3.5.4. Lead the IRB through a discussion of the criteria in applicable worksheets.
 - 4.3.5.5. When a checklist is applicable, discuss the checklist determinations and study-specific findings supporting those determinations.
 - 4.3.5.6. Summarize the IRB's consensus.
- 4.3.6. Make or have an IRB member make a motion for one of the following:
 - 4.3.6.1. "Approve": When the IRB determines that the research meets or still meets the criteria for approval.
 - 4.3.6.1.1. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review (not to exceed one year).
 - 4.3.6.1.2. If the research is subject to <Revised Requirements> and continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)", but the IRB requires continuing review, provide the IRB's rationale for requiring continuing review.²
 - 4.3.6.1.3. Document that the criteria for approval are met or still met.
 - 4.3.6.2. "Conditionally Approve": When the IRB determines that the research will meet or still meets the criteria for approval with minor or prescriptive changes or requirements that can be verified without considering the criteria for approval.³
 - 4.3.6.2.1. For initial and continuing review, include in the motion, the level of risk (minimal risk or greater than minimal risk), and either that continuing review is not required, or the period of continuing review (not to exceed one year).
 - 4.3.6.2.2. If the research is subject to <Revised Requirements> and continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)", but the IRB requires continuing

² When research is FDA-regulated and subject to the <Revised Rule>, the IRB's rationale for requiring continuing review is that the research is FDA-regulated.

³ Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.

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- review, provide the IRB's rationale for requiring continuing review.
- 4.3.6.2.3. Summarize the IRB's required modifications and reasons.
- 4.3.6.2.4. Document that if the conditions are satisfied, the criteria for approval will be met or are still met.
- 4.3.6.3. "Defer": When the IRB determines that the initial, continuing, or amendment submission does not meet the criteria for approval and does not meet the criteria for "Disapprove".
 - 4.3.6.3.1. Summarize the IRB's reasons and recommendations, if any.
- 4.3.6.4. "Disapprove": The initial, continuing, or amendment submission does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies.
 - 4.3.6.4.1. Summarize the IRB's reasons and recommendations, if any.
- 4.3.6.5. "Suspend": When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.
 - 4.3.6.5.1. Include in the motion: Which research activities must stop or be modified
 - 4.3.6.5.2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment
 - 4.3.6.5.3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed
 - 4.3.6.5.4. Lead the IRB members through a discussion of "WORKSHEET: New Information (HRP-411)" to consider additional actions.
 - 4.3.6.5.5. Summarize the IRB's reasons and recommendations.
- 4.3.6.6. "Terminate": When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.
 - 4.3.6.6.1. Lead the IRB members through a discussion of "WORKSHEET: New Information Items (HRP-411)" to consider additional actions.
 - 4.3.6.6.2. Summarize the IRB's reasons.
- 4.3.6.7. "Lift Suspension": When the IRB determines that based on an amendment submission or new information the previously suspended research meets the criteria for approval.
- 4.3.6.8. "Pull": The research will be removed from the meeting agenda.
- 4.3.6.9. "Withdraw Approval"/"Rescind Approval": A prior approval of a document, site, investigator, and so forth was incorrect and can be withdrawn. The research may continue as it did before the approval.
- 4.3.6.10. "Approve in Principle": When a federal funding agency requires IRB approval before the funding agency can release grant monies, and the investigator cannot submit a complete research proposal, the IRB may provide a preliminary opinion on the proposed research.

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- 4.3.6.11. "Accept/Acknowledge": The IRB wants to confirm that the IRB has reviewed the materials, but an action of "Approve" is not applicable.
- 4.3.7. Ensure that the HRPP staff member taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations, and findings.
- 4.3.8. Call for a vote of IRB members "For," "Against," or "Abstaining." If more than half the IRB members present votes "For," the motion is approved.
 - 4.3.8.1. Treat a tie vote to approve a motion for "Approve" or "Conditionally Approve" as an IRB decision of "Defer."
- 4.3.9. Have individuals with a <Conflicting Interest> rejoin the meeting.
- 4.4. Adjourn the meeting when there is no further business or when notified by an HRPP staff member that quorum for all remaining agenda items cannot be met.
 - 4.4.1. If there are remaining agenda items, move them to another meeting.

5. REFERENCES

- 5.1. 21 CFR §56.109
- 5.2. 45 CFR §46.109
- 5.3. OHRP Guidance on IRB Approval of Research with Conditions