UNIVERSITY OF MIAMI	SOP: IRB Meeting Conduct				
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1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.
1.2 The process begins when the IRB members gather for a convened meeting.
1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 11/13/2013
2.2 08/08/2014
2.3 06/13/2014
2.4 11/23/2014
2.5 Added language to describe the process for alternates who are substituting for Core member who is present.
2.6 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 All IRB Members will have access to the same review materials whether they attend in person or remotely via an electronic mechanism.
3.2 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
3.3 The IRB chair votes as a regular member.
3.4 Meetings are conducted in person or via teleconference.
3.5 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest.
3.6 IRB members who have a conflict of interest with the research under review may participate in the review but must leave the room or be placed on hold during the deliberation and vote.
3.7 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
3.8 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.
3.9 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
3.10 The worksheets and checklists described in HRP-301 - WORKSHEET - Review Materials and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.
3.11 Worksheets containing the criteria for approval and other materials being reviewed are projected by HSRO staff upon request of an IRB Member.

4 RESPONSIBILITIES

4.1 The IRB chair, Vice-Chair or other designee carries out these procedures.
4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.
4.3 HSRO Staff provide review materials to the IRB members, monitor quorum, and ensure agenda is completed.

5 PROCEDURE

5.1 Call the meeting to order.
5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.

5.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.

5.4 For each business item:

5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Quorum and Expertise are not met.[1]

5.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.

5.4.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.

5.4.4 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

5.4.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

5.4.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria in HRP-314 - WORKSHEET - Criteria for Approval and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

5.4.7 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

5.4.7.1 Have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.4.7.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.4.7.3 Make a motion for the IRB's determination(s) regarding the action items (e.g. the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

5.4.8 If a conflict of interest exists, review the conflict.

5.4.8.1 If a management plan has been approved by the Conflict of Interest Committee (COIC), consider whether the plan adequately eliminates/reduces the risk of bias.

5.4.8.2 If the management plan has not yet been approved by the COIC, the IRB has two options:

5.4.8.2.1 Assign a management plan and require the investigator to adhere to the plan.

5.4.8.2.2 Table the review pending receipt of the management plan.

5.4.8.3 If the first option is chosen:

5.4.8.3.1 HSRO staff will obtain the management plan developed by the COIC and compare that plan to the plan developed by the IRB for consistency.

5.4.8.3.2 If the COIC-approved plan is identical to or more stringent than the IRB approved plan, HSRO staff may give final approval to the submission if all other requirements to secure approval are met 5.3.8.3.2.1 The IRB approval letter will require the investigator to comply with the plan developed by the COIC.

[1] "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.

5.4.8.3.3 If the COIC-approved plan is less stringent than the IRB approved plan:

5.4.8.3.4 HSRO staff will notify the COIC of the discrepancy and determine whether there is additional information relating to the conflict for IRB review;

5.4.8.3.5 If additional information exists, HSRO staff will schedule the submission for IRB Committee review for reconsideration.

5.4.8.3.6 If additional information does not exist, the IRB's determination will stand and the IRB approval letter will include the COI management plan determined by the IRB.

5.3.8.3.6.1 HSRO will send a copy of the approval letter to the COIC.

5.4.9 The Chair or presenter will restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

5.4.10 Make a motion for one of the following actions:

5.4.10.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

5.4.10.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes

5.4.10.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.

5.4.10.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

5.4.10.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.4.11 Review any modifications required to secure approval to ensure that the HRSO staff has recorded them.

5.4.12 Call for a vote.

5.4.12.1 Only IRB members may vote

5.4.12.2 The IRB Chair and Vice-Chair are voting members of the IRB

5.4.12.3 If a core member and an alternate who is substituting for a core member on an agenda item are both present at a meeting:

5.4.12.3.1 Before the IRB begins the presentation of the agenda item, the core member will automatically go out of voting status and the alternate member will automatically move into voting status for that agenda item.

5.4.12.3.2 Following the vote, the alternate member will automatically move out of voting status and the core member for whom the alternate member substituted will move back into voting status.

5.4.12.4 Consultants may not vote.

5.4.12.5 For a motion to be approved, it needs the approval of more than half of the members at the meeting (If 9 members are present, 5 votes are required for approval)

5.4.12.6 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.4.12.7 Provide any written information provided by a member or consultant to the HSRO staff

5.4.12.8 Provide any written information provided by a member or consultant to the IRB staff.

5.4.12.9 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation
6.2 HRP-301 - WORKSHEET - Review Materials
6.3 HRP-305 - WORKSHEET - Quorum and Expertise
6.4 HRP-308 - WORKSHEET - Pre-Review
6.5 HRP-314 - WORKSHEET - Criteria for Approval
6.6 HRP-315 - WORKSHEET – Advertisements
6.7 HRP-316 - WORKSHEET – Payments
6.8 HRP-317 - WORKSHEET - Short Form of Consent Documentation
6.9 HRP-318 - WORKSHEET - Additional Federal Agency Criteria
6.10 HRP-321 - WORKSHEET - Review of Information Items
6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD
6.12 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
6.13 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
6.14 HRP-412 - CHECKLIST - Pregnant Women
6.15 HRP-413 - CHECKLIST - Non-Viable Neonates
6.16 HRP-414 - CHECKLIST - Neonates of Uncertain Viability
6.17 HRP-415 - CHECKLIST - Prisoners
6.18 HRP-416 - CHECKLIST - Children
6.19 HRP-417 - CHECKLIST - Cognitively Impaired Adults
6.20 HRP-418 - CHECKLIST - Non-Significant Risk Device
6.21 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

7 REFERENCES

7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
7.2 45 CFR §46.109, §46.116, §46.117.
7.3 AAHRPP elements I.1.F, I.5.A, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3