		SOP
Department	**Title**	**Dates**
Research Integrity and Protection	IRB Meeting Conduct	Effective: 1/7/2019
		Approved: 1/3/2018
SOP ID		Last Revised: 1/3/2019
IRB-SOP-402		Expiration: n/a

PURPOSE

This procedure establishes the process to conduct convened meetings.

SCOPE

This procedure applies to all convened meetings of any Ascension Wisconsin IRB.

DEFINITIONS

Quorum A quorum is defined as more than half of the regular voting members. A quorum consists of regular members or their alternate and includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.

Conflicting Interest An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's Immediate Family have any of the following: 1) Involvement in the design, conduct, or reporting of the research; Ownership interest, stock options, or other ownership interest Related to the Research of any value exclusive of interests in publicly-traded, diversified mutual funds; Compensation Related to the Research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research; Proprietary interest Related to the Research including, but not limited to, a patent, trademark, copyright or licensing agreement; or, Any other reason for which the individual believes that he or she cannot be independent. See SOP: Definitions (SOP-001).

PROCESS

1. **Quorum and Voting**
   - 1.1. The IRB meeting may not convene until quorum is established. IRB staff will inform the IRB Chair when quorum has been established. "WORKSHEET: Evaluation of Quorum and Expertise (WRK-501)" may be consulted to determine that the meeting is appropriately convened.
   - 1.2. Only IRB Members may count towards meeting the quorum requirements and vote.
   - 1.3. The IRB chair, including co-chair or vice chair, votes as a regular member and are counted towards meeting the quorum requirements.
   - 1.4. 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.
   - 1.5. Consultants may not be used to establish a quorum and may not vote.
   - 1.6. If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored.

2. Meeting Attendance Monitoring

2.1. IRB staff is responsible for monitoring the meeting for late arrivals and departures of members. "WORKSHEET: Evaluation of Quorum and Expertise (WRK-501)" may be consulted at any time to determine that the meeting is appropriately convened.

2.2. Before each protocol, staff ensures that the meeting is appropriately convened by meeting the quorum and expertise requirements, and notifies the IRB chair when the meeting is not appropriately constituted for the review of that protocol.

2.3. When a member leaves the meeting room for any reason, staff ensures that the meeting is appropriately convened by meeting the quorum and expertise requirements, and notifies the IRB chair when the meeting is not appropriately constituted for the review of that protocol.

2.4. For each vote, attendance is taken for all members being counted towards meeting the quorum requirements and casting a vote. The IRB chair is notified when the meeting is not appropriately constituted for the review of that protocol.

3. Actions the IRB May Take

3.1. Approve (with a specific continuing review interval for initial or continuing review): 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.

3.2. Approval Pending Required Revisions (with a specific continuing review interval for initial or continuing review): 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 reviewer restates or confirms the modifications required by the IRB members and the IRB member's reasons for those changes.

3.3. Defer: Made when the research does not qualify for Approval or Approval Pending Required Revisions 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.

3.4. 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, including the regulatory criteria not satisfied.

3.5. Suspension or Termination: 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 the "WORKSHEET: Review of Information Items (HRP-321)" 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.

4. Meeting Procedures

4.1. Once quorum is met, call the meeting to order.

4.2. Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.

4.3. 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.

4.4. For each item involving review of a protocol:

4.4.1. Table the item when notified by IRB staff when requirements for review of a specific item as defined in WORKSHEET: Quorum and Expertise are not met.

4.4.2. 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.

4.5. For each agenda item involving the initial review, modification or continuing review of a protocol:

4.5.1. If there is a consultant present, ask the consultant to present his or her review to the IRB, or if a consultant provided written information to the IRB, present that information to the IRB.

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

4.5.3. Ask the primary reviewer to lead the IRB through a discussion of the criteria approval as outlined on the reviewer checklist, completed in Mentor, 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.

4.5.4. Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

4.5.5. Make a motion for the IRB Action.

4.5.5.1. The reviewer explicitly states that, in his/her opinion, the criteria required for approval have been met; and

4.5.5.2. The reviewer proposes a specific frequency for continuing review, when applicable, if the initial application is an initial application or Continuing Report.

4.5.5.3. 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.

4.5.5.4. Minor or prescriptive changes or requirements (revisions required to secure approval) may be reviewed for approval by the IRB staff or IRB chair, other designated individual.

4.5.6. Open the floor for additional discussion.

4.5.7. Review any revisions required to secure approval to ensure that the IRB staff has recorded them.

4.5.7.1. Ensure that the required revisions include all final contingencies on the IRB pre-review checklist.

4.5.7.2. For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

4.5.8. Call for a vote.

4.5.8.1. For a motion to be approved, it needs the approval of more than half of the members present at the meeting.

4.6. 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):

4.6.1. Have the primary reviewer use the Reviewer checklist in Mentor to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

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

4.6.3. 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) and open the floor for additional discussion.

4.7. Call for a vote.
4.8. Re-invite IRB members with a Conflicting Interest back into the meeting.
4.9. Provide any written information provided by a member or consultant to the IRB staff.
4.10. Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

REFERENCES

- 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
- 45 CFR §46.109, §46.116, §46.117.

RELATED MATERIALS

- IRB Pre-Review Checklist (in Mentor)
- CHECKLIST: Waiver or Alteration of Consent Process (CK-301)
- CHECKLIST: Waiver of Written Documentation of Consent (CK-401)
- CHECKLIST: Pregnant Women (CK-501)
- CHECKLIST: Non-Viable Neonates (CK-601)
- CHECKLIST: Neonates of Uncertain Viability (CK-701)
- CHECKLIST: Prisoners (CK-801)
- CHECKLIST: Children (CK-901)
- CHECKLIST: Cognitively Impaired Adults(CK-1001)
- CHECKLIST: Non-significant Risk Device (CK-1101)
- CHECKLIST: Waiver of Consent for Emergency Research (CK-1201)
- SOP: IRB Meeting Preparation (SOP-401)
- WORKSHEET: Review Materials (WRK-101)
- WORKSHEET: Quorum and Expertise (WRK-501)
- WORKSHEET: Pre-Review (WRK-308)
- WORKSHEET: Criteria for Approval (WRK-1201)
- WORKSHEET: Advertisements (WRK-1300)
- WORKSHEET: Payments (WRK-1301)
- WORKSHEET: Short Form of Consent Documentation (WRK-1401)
- WORKSHEET: Additional Federal Agency Criteria (WRK-2101)
- WORKSHEET: Criteria for Approval for HUD (WRK-1801)
- WORKSHEET: Reportable Events (WRK-1601)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	12/22/17	New- Initial Integration Update	J. Blundon
02	11/7/2018	1.4 Added allowable attendance formats; 4.3.8. Updated steps for a motion of IRB action; minor editorial corrections; 4. reorganization and clarifications	J. Blundon-Kirchen