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1. PURPOSE

- 1.1. This document describes the **policy** and **procedures** that the University of Georgia Institutional Review Board (UGA IRB) follows during a meeting of the convened Board.

2. DEFINITIONS

- 2.1. **Recusal:** an IRB Member's absence from the IRB meeting due to a **conflicting interest** in the item under consideration. This Member will not count towards the **quorum**.

3. POLICY

- 3.1. The meeting can only be called to order when **quorum** requirements have been met, as defined in *Worksheet: Quorum and Expertise*.
 - 3.2. Members participating by teleconference, videoconference or similar technology must be able to actively and equally participate in a discussion, as well as access study materials and review checklists.
 - 3.3. Members who have conflicting interests with an item being reviewed must recuse themselves and leave the room during discussion (except to provide additional information) and vote on such item and cannot be counted toward quorum. See *Policy and Procedures: Conflicting Interest of IRB Members and Consultants*.
 - 3.3.1. Recusals are indicated in the minutes as "Recusal."
 - 3.4. Members may leave the meeting (an absence) for reasons other than a conflicting interest. An absence must not count towards quorum and must be noted in the meeting minutes.
 - 3.5. If the quorum requirements are not met for an agenda item, votes cannot be taken until the quorum is restored. If quorum is not restored, the item must be tabled.
 - 3.6. The **Principal Investigator (PI)** or a Study Team Member may be present or available by phone to provide study related information. The clarifying information may be requested from the PI, and this may occur before, during, or after the meeting through several mechanisms.
 - 3.7. The **Primary Reviewer** must lead the discussion of approval criteria and any specific determinations that the IRB is required to make.
 - 3.7.1. If the Primary Reviewer is not present at the meeting and there is a **Secondary Reviewer**, the Secondary Reviewer shall assume his/her duties.
 - 3.7.2. If both the Primary or Secondary Reviewers are not present but they have provided a written review, the IRB Chair can present the information and lead the discussion. Note: This is only appropriate when quorum requirements have been met.
 - 3.8. The IRB may make one of the following actions and determinations as a result of its review:
 - 3.8.1. **Approve:** an IRB action taken when no modifications to the submission are required; all criteria for approval of **research** and required determinations have been met.
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- 3.8.2. **Approve with Modifications Required to Secure Final Approval:** means that at the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the **Investigator** (a) makes specified changes to the research protocol or informed consent document(s), (b) confirms specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submits additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval.
- 3.8.3. **Defer:** an IRB action taken when the IRB cannot fully evaluate the research under review and make the determinations required for approval without significant modifications to the protocol and/or informed consent document, or submission of clarifications or additional information/materials. The IRB will include in its written notification a statement of the reasons for this decision and give the **Investigator** an opportunity to respond in person or in writing. Investigator deferral responses require review by the convened IRB.
- 3.8.4. **Disapprove:** an action made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. The IRB will include in its written notification the reasons for this decision and give the Investigator an opportunity to respond to the IRB in person or in writing.
- 3.8.5. **Table:** is not an action of the IRB, but is a determination based on the inability of the IRB to initiate or complete a review (usually due to reasons of quorum).
- 3.8.6. **Suspend or Terminate IRB Approval:** see *Policy and Procedures: Suspensions or Terminations of IRB Approval*.
- 3.9. If the IRB approves research with major modifications or substantive clarifications, requires additional information, or raise other issues that are directly related to the determinations whether the criteria for approval have been satisfied, a review and approval by the IRB at a subsequent convened meeting is required (i.e., it cannot be approved by the IRB Chair or Designated IRB Member).
- 3.10. If the IRB approves research with minor or prescriptive modifications or conditions required to secure approval, the IRB may designate the IRB Chair or other IRB member(s) with appropriate expertise or qualifications to review the responsive materials and determine that the conditions have been satisfied; further review by the IRB at a subsequent convened meeting would not be necessary.
- 3.11. If none of the reviewers assigned to review the item is present at the meeting, no written review has been provided in advance of the meeting, and no other IRB Member present has conducted a thorough review, the item must be tabled and rescheduled for presentation at the next meeting.
- 3.12. IRB determinations and actions to be taken are recorded as motions and followed by voting.
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- 3.13. Votes are signified by raised hands, by voice, or available nonverbal feedback features if participating by teleconference.
- 3.14. A meeting must be adjourned when quorum has been permanently lost or when there is no further business to discuss.

4. PROCEDURES: IRB Staff

- 4.1. The IRB Staff must distribute or display the study materials and approval criteria checklist.
- 4.2. The IRB Staff must provide a copy of the Chair Agenda to the IRB Chair and other members as needed.
- 4.3. The IRB Staff must record sufficient notes during discussion pertaining to agenda items to later prepare the meeting minutes.
- 4.4. IRB Staff must inform the IRB Chair if quorum is not present for a vote.
- 4.5. The Designated IRB Staff Member must record the attendance, recusals and/or absences, motions, relevant details, determinations, risk level, approval interval, and voting in the minutes. Attendance includes each member's status as a scientist, non-scientist, and/or community member who is unaffiliated with the institution, as well as areas of expertise.

5. PROCEDURES: IRB Chair

- 5.1. The IRB Chair must call the meeting to order.
- 5.2. The IRB Chair must remind the Members, IRB Staff, and any Guests that although records may be subject to Open Records Act, the discussion and votes should be kept confidential.
- 5.3. The IRB Chair must introduce any Observers or Guests.
- 5.4. The IRB Chair must ask the Members for questions and/or discussion on the previous meeting minutes and any **expedited** studies that were reviewed within the past 45 days.
- 5.5. The IRB Chair facilitates conduct of other business, which includes but is not limited to education and announcements.
- 5.6. The IRB Chair must ask if any Members have a conflicting interest with respect to any of the items to be reviewed.
- 5.7. For each agenda item involving review of a protocol:
 - 5.7.1. The IRB Chair must recuse any Member that has a conflicting interest in respect to an item.
 - 5.7.2. If a Consultant is present, the IRB Chair must ask the Consultant to present his or her review to the IRB. See *Policy and Procedures: Consultation to the IRB*.
 - 5.7.3. If a Consultant provided written information to the IRB, the IRB Chair or Designee must present that information to the IRB.



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- 5.7.4. The IRB Chair must direct the Primary Reviewer to provide a short descriptive summary of the item, the scientific or scholarly review summary, and to lead discussion of the approval criteria using *Worksheet: Criteria for Approval* as a guide.
- 5.7.5. The IRB Chair must direct the Secondary Reviewer for additional review information.
- 5.7.6. If the item is a Report of New Information, the IRB Chair must direct the Primary Reviewer to use the *Worksheet: Review of Information Items* to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.
- 5.7.7. When additional information or clarification is needed in order to make determinations and the PI or Proxy is present, the IRB Chair must invite him/her to join the discussion.
- 5.7.8. The IRB Chair must excuse the PI/Proxy prior to final discussion of action/s to be taken.
- 5.7.9. The IRB Chair or another member may make a motion and additional discussion may follow. The Worksheet - Meeting Approval Criteria and Determination will be reviewed before a vote is taken.
- 5.7.10. The IRB Chair must facilitate additional discussions and summarize the motion. The motion must include:
 - 5.7.10.1. The action or determination to be taken: See 3.8 above.
 - 5.7.10.2. If the action is Modifications Required to Secure Final Approval, a summary of the required modifications and designation of the individual/s responsible for review of responsive materials.
 - 5.7.10.3. For initial studies and continuing reviews, the period of approval and level of risk.
- 5.7.11. The IRB Chair must request the Member with expertise in regulatory affairs to present and lead discussion of any specific determinations pertaining to: alterations of informed consent, waiver of the requirement to obtain informed consent, waiver of the requirement to document informed consent, device risk, or other determinations as required by regulations.
- 5.7.12. The IRB Chair must call for a vote.
 - 5.7.12.1. For a motion to be approved, it must receive the approval of more than half of the Voting Members present.
- 5.7.13. The IRB Members with conflicting interests must be invited back to join the meeting.
- 5.8. The IRB Chair must adjourn the meeting when notified by IRB Staff that quorum has been lost or when there is no further business.

6. MATERIALS

- 6.1. Worksheet: Meeting Approval Criteria and Determinations
 - 6.2. Worksheet: Quorum and Expertise
 - 6.3. Worksheet: Review of Information Items
 - 6.4. TEMPLATE: Chair Agenda
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7. REFERENCES

- 7.1. 45 CFR §46.108(b) and 21 CFR 56.108(c)
- 7.2. OHRP Guidance on IRB Approval of Research with Conditions
- 7.3. OHRP Memorandum, "IRB Meetings Convened Via Telephone Conference Call," March 28, 2000
- 7.4. Policy and Procedures: Conflicting Interest of IRB Members and Consultants
- 7.5. Policy and Procedures: Consultation to the IRB
- 7.6. Policy and Procedures: Suspensions or Terminations of IRB Approval

Revision History:

09/18/2015: REV0 New Document

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