



Policy Title	IRB Meeting Conduct
Last Updated	2-16-2021
Responsible Office	IRB Office
Contact Information	IRB Office Email: irb@kennesaw.edu Phone: 470-578-4941

1. Policy Purpose Statement

The purpose of this policy and procedure is to describe the actions and conduct of IRB meetings at Kennesaw State University.

2. Definitions

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

3. Policy

- 3.1. The meeting can only be called to order when quorum requirements have been met.
- 3.2. All members must be provided access to all items for consideration prior to the meeting.
- 3.3. All members must come to the meeting prepared to discuss each item for consideration on the agenda and be able to actively and equally participate in a discussion.
- 3.4. Members who have conflicting interests with an item on the agenda must announce said conflicting interest prior to discussion of the item and recuse themselves from discussion and vote. The member will not count toward quorum for the item in which there is a conflicting interest.
- 3.5. Members may leave the meeting for reasons other than a conflicting interest. This will be considered an absence for any items discussed and voted on during this time. An absence will not count toward quorum and will be documented in the meeting minutes. Quorum must be maintained in order for any further IRB business to proceed.
- 3.6. The Primary Reviewer will lead the discussion of approval criteria and any specific determinations that the IRB is required to make.
 - 3.6.1. If the Primary Reviewer is not present at the meeting and there is a Secondary Reviewer, the Secondary Reviewer will assume this duty.
 - 3.6.2. If both Primary and Secondary Reviewer are not present but they have provided a written review, the IRB Chair can present the information and lead the discussion.
- 3.7. The IRB may make one of the following actions and determinations as a result of this review:
 - 3.7.1. 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.
 - 3.7.2. Approve with modifications required to secure final approval: an IRB action taken when the IRB reviews and approves a research study (or proposed changes to a previously approved research study) and requires as a condition of approval that the investigator make specified changes to the research protocol or informed consent document(s). The IRB may designate the IRB Chair or other IRB member(s) with appropriate expertise or qualifications to review the changes submitted by the PI and determine that the conditions have been satisfied.
 - 3.7.3. 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(s), or submission of clarifications or additional information/materials. The IRB will include in its notification of deferral to the PI reasons for this decision and provide an opportunity to respond. The investigator must provide adequate responses to each reason for deferral in order for the IRB to review the submission again at a future meeting.

- 3.7.4. Disapprove: an action taken 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 notification of disapproval to the PI reasons for this decision and provide an opportunity for the PI to respond. Changes made to the submission must be determined adequate by the IRB Chair before the submission will be considered for the IRB to review again at a future meeting.
- 3.7.5. Table: not an action of the IRB, but is a determination based on the inability of the IRB to initiate or complete a review.
- 3.7.6. Suspend or Terminate IRB Approval:
- 3.8. IRB determinations and actions to be taken are recorded as motions and followed by voting and recorded in the meeting minutes as for, against, abstained, absent.
- 3.9. Meetings will be adjourned with quorum is lost or when there is no further business to discuss.

4. Procedures

- 4.1. The IRB Chair will call the meeting to order.
- 4.2. The IRB Chair should remind those in attendance that discussion and votes should be kept confidential.
- 4.3. When there are visitors or new members present, the IRB Chair will initiate introductions.
- 4.4. The IRB Chair will ask members if there are any questions or items for discussion related to the previous meeting minutes and any expedited studies that were reviewed within the prior 45 days which made available to all members, present or not, primary or alternate prior to each convened meeting.
- 4.5. The IRB Chair will introduce persons who will provide any training or announcements identified on the meeting agenda.
- 4.6. The IRB Chair must ask if any members have a conflicting interest with respect to any of the items on the agenda.
- 4.7. For each protocol on the agenda for review:
 - 4.7.1. The IRB Chair will ask any member who has announced a conflicting interest to recuse and take appropriate actions to remove themselves from the discussion and vote.
 - 4.7.2. The IRB Chair will direct the Primary Reviewer to provide a summary of the protocol and scientific or scholarly review observations/items for discussion.
 - 4.7.3. The IRB Chair will ask the Secondary Reviewer to provide additional items for consideration.
 - 4.7.4. The IRB Chair will lead the discussion of the approval criteria.
 - 4.7.5. All members will use approval criteria requirements as a basis for discussion.
 - 4.7.6. When additional information is needed in order to make determinations required for approval, the IRB Chair will invite the PI or proxy into the meeting if available and then excuse the PI or proxy prior to any further deliberation of the IRB and action.
 - 4.7.7. The IRB Chair will use and direct other members to refer to provided checklists for approval criteria and other determinations to be made prior to calling for a motion for an action to be taken.

- 4.7.8. The IRB Chair will facilitate additional discussion and summarize the motion. The motion must include:
 - 4.7.8.1. The action or determination to be taken.
 - 4.7.8.2. 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 response from the PI.
 - 4.7.8.3. For initial studies and continuing review, the period of approval and level of risk.
- 4.7.9. The IRB Chair will request a member of the IRB Office to present 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, or other determinations as required by the regulations.
- 4.7.10. The IRB Chair will call for a vote. For a motion to be approved, it must receive approval from more than half of the voting members present.
- 4.8. When all items on the agenda have been addressed, the IRB Chair will adjourn the meeting.