Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

IRB Meeting Conduct

(UGAHRP-041-4)

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Definitions

- **Primary Reviewer** – assigned reviewer to a study to lead the discussion of approval criteria and any specific determinations that the IRB is required to make

- **Secondary Reviewer** – assigned reviewer to a study to give additional review information. S/he will assume the duties when the primary reviewer is absent

- **Voting Member** – when both a regular member and his/her designated alternate attend a meeting, only one may count toward the quorum and may vote on any specific protocol

Definitions

- **Recusal** – members who have conflicting interest 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

- **Abstention** – when a member does not have a COI but feels that s/he should not vote on a study
  - E.g., Member was not present during the important discussions about the study
  - If a member was present for discussions of important issue but still not comfortable approving the study, s/he should register a vote to not approve

UGA IRB MEMBERS (2022-2023)

IRB 1	IRB 2
• Regular - 7 • Alternate - 15	• Regular - 7 • Alternate - 10

- **Quorum** – minimum number of members to hold meetings or make decisions during meeting
  - For both IRBs the quorum is **4**

The IRB may make one of the following actions and determinations as a result of its review

- **Approve** – no modifications to the submission are required; all criteria have been met

- **Approve with Modifications Required to Secure Final Approval** – at the time when the IRB reviews and approves a research study, the IRB requires as a condition of approval that the PI

  (a) Makes specified changes to the research protocol or informed consent document(s),

  (b) Confirms IRB's specific assumptions or understandings on 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

The IRB may make one of the following actions and determinations as a result of its review (cont.)

- **Defer** – 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
- PI's deferral responses require review by the convened IRB
- **Disapprove** – 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 may make one of the following actions and determinations as a result of its review (cont.)

- The IRB will include in its letter the reasons for the deferral or disapproval decision and give the PI an opportunity to respond in person or in writing

- **Table** – is not an IRB action, but a determination based on the inability of the IRB to initiate or complete a review (usually due to reasons of quorum)

- The item must be **tabled** and rescheduled for presentation at the next meeting
  - If both reviewers assigned to review the item are absent,
  - No written review has been provided in advance of the meeting, and
  - No other IRB Member present has conducted a thorough review

The IRB may make one of the following actions and determinations as a result of its review (cont.)

- **Suspend or Terminate IRB Approval** –
  - Suspension – to temporarily withdraw IRB approval of some or all research activities
  - Termination – to permanently withdraw IRB approval of some or all research activities

- When the IRB suspects or determines that any of the following has occurred:
  - An unanticipated problem involving risks to subjects or others
  - The research is not being conducted in accordance with the IRB requirements with possible risk of harm to research participants, &/or
  - Serious or continuing non-compliance

IRB Reminder

- If the IRB approves research with the following, a review and approval by the convened IRB at a subsequent meeting is required:
  - 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
- It cannot be approved by the IRB Chair or Designated IRB Member

IRB Reminder (cont.)

- 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

- IRB determinations and actions to be taken are recorded as motions and followed by voting
  - The minor or prescriptive modifications or conditions required to secure approval must be clearly stated in the record and minutes. State the required modifications clearly and be as prescriptive as possible
    OR Describe parameters for acceptable responses

IRB Meeting Procedure

1. Call to order
2. Reminder that discussion and votes should be kept confidential
3. Introduction of observers/guests
4. Questions/Discussions on previous minutes and any expedited studies reviewed within the past 45 days
5. Announcement and training
6. Conflict of Interest (COI) statement
   - For each agenda item, recuse any member with COI
7. Review of agenda items
   - Consultant review presentation
   - Primary and Secondary Reviewer presentation
     - If the item is a **Report of New Information (RNI)**, the IRB Chair must direct the Primary Reviewer to use the *Worksheet: Review of Information Items* to lead the IRB through a discussion of what actions are needed, if any, to protect subjects
8. PI joins meeting to clarify items or answer questions
9. Motion and additional discussion

IRB Meeting Procedure (cont.)

10. *Approval of Criteria Worksheet* review

11. IRB Chair to summarize the motion, which includes:
    - Action or determination to be taken
    - A summary of the required modifications and designation of the individual/s responsible for review of responsive materials (if action is Mod Req to Secure Final Approval)
    - Period of approval and risk level (for initial and continuing review)

13. IRB Chair to request 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

14. Call for a vote

15. Meeting adjourn

MEMORY REVIEW

Memory Review

- There was a concern on how the study team was trained to use the device. How practical training is completed (who was the subject of the “practice”)?

- The TMS study approved in March determined that the device will only be used as a tool to collect data and not to test its safety and/or effectiveness, so Significant Risk or Non-Significant Risk determination by the IRB was not necessary

- Because PI sees many student-athletes in his lab, there is potential that they may be included in the study and the IRB recommended extra protections as required by UGA policy

Helpful Links/Resources:

- UGAHRP-026-1 – Suspension or Terminations of IRB Approval
- UGAHRP-041-4 - IRB Meeting Conduct
- UGAHRP-042-2 - IRB Meeting Attendance Monitoring
- UGAHRP-044-0 – Review of Not Otherwise Approvable Research
- UGAHRP-050-2 – Conflicting Interests of IRB Members and Consultants
- **IRB Member Resources – Archived Presentations - July 7, 2021 and December 8, 2021 Modifications Required to Secure Approval**

Thank you!