University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #6	**TITLE: The Conduct of IRB Meetings**		**Page 1 of 4**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-12-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 05-09-19

OBJECTIVE

To describe policies and procedures for the preparation, scheduling, and conduct of convened meetings of the Institutional Review Board (IRB)

GENERAL DESCRIPTION

The University of Kentucky IRB conducts convened meetings in accordance with applicable federal requirements for full review (i.e., 21 CFR 56.108, 45 CFR 46.108)

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB Members, Office of Research Integrity (ORI) Staff; Principal Investigator (PI)/Study Personnel

PROCEDURES

Preparation and Distribution of the Agenda

1. ORI staff develop, maintain, and revise the IRB meeting schedule, as appropriate. The meetng dates are available on the ORI website or by request. ORI staff coordinate meeting rooms and catering arrangements after confirming the meeting dates.

2. ORI staff create an agenda approximately five (5) to ten (10) days before a meeting. ORI staff review the agenda for accuracy and completeness before making it available to members of the appropriate IRB.

3. If special circumstances exist, ORI staff prepare an addendum to the agenda and make it available to IRB members prior to the meeting.

4. ORI staff make the agenda and related materials available to other appropriate individuals (e.g., Investigational Drug Service Director, HIPAA Privacy Specialist, Radiation Safety Officer).

5. ORI staff notify PIs of appointment times for initial full review protocols.

6. The agenda serves as a guideline for the conduct of the meeting. The agenda for the meeting may include additional discussion items at the discretion of the IRB Chair, ORI staff, or IRB members.

Quorum Requirements

1. A majority (e.g., IRB members = 11; majority = 6) of the IRB members must be present.

2. At least one member whose primary concerns are in nonscientific areas is present at the convened meeting.

3. A licensed physician member must be present when the IRB reviews FDA-regulated research.

4. Alternate members may attend in place of absent regular members in order to meet quorum requirements. (See Membership of IRB SOP.)

5. The IRB does not consider ad hoc and cultural consultants to establish a quorum.

6. Members excuse themselves from the meeting during a vote when they have a conflict of interest. In such cases, they do not count towards the number necessary to constitute a vote or majority. If quorum is lost during a meeting (e.g., loss of a majority through excused members with conflicting interests or early departure or absence of a non-scientist member, etc.), the IRB does not take further protocol actions that require a vote unless quorum is restored.

Review of Protocols

1. The IRB Chair, Vice Chair, or any voting IRB member may chair the convened meeting.

2. For initial full review, the IRB requires that PIs attend the convened meeting. The IRB, IRB Chair, or ORI staff may grant permission for the co-investigator or knowledgeable party to attend in place of the PI. The IRB, IRB Chair/Vice Chair, or ORI staff may also waive this attendance requirement.

3. For other types of review, IRB members, the IRB Chair, or ORI staff may also invite or require the PI to attend, when deemed appropriate.

4. ORI staff or the IRB Chair may grant permission for attendance by observers upon request. Faculty make requests on behalf of student observers to the ORI. Upon receipt of any request, ORI staff or the IRB Chair use discretion to grant permission for attendance to selected meetings by observers. ORI staff or the IRB Chair make meeting selections based on availability and agenda suitability. ORI staff obtain a statement of confidentiality from observers who have permission to attend. ORI does not provide observers with copies of application materials.

5. IRB members do not participate in the review of any component of a project in which the member has a conflict of interest, except to provide information requested by the IRB. (See IRB Member and Consultant Conflict of Interest SOP)

6. For discussion of review outcomes and controverted issues, see Initial Full Review, Continuation Review, Protocol Violations, Modification, Deviations and Exceptions-IRB Review of Changes, and Noncompliance SOPs.

7. ORI staff are responsible for preparing meeting minutes. (See Minutes of IRB Meeting SOP.)

Tele/Videoconference Participation

1. The IRB may conduct convened meetings by telephone or video conferencing as long as IRB member(s) have been provided with prior access to all of the materials to be reviewed at the meeting, a quorum as defined above is present, and discussion occurs in real time.

2. Members participating via tele/videoconferencing count as part of the quorum and may vote. "Telephone polling" (where ORI staff or others contact IRB members individually by telephone) does not qualify as a convened meeting. To allow for appropriate discussion, all members must be connected and able to participate simultaneously for a tele/videoconference to take place.

Voting

1. IRB members may not vote by proxy (i.e., members not present at the convened meeting or participating in the tele/videoconference call may not vote on an issue discussed during a convened meeting). However, members can provide written comments for IRB consideration.

2. Voting at a convened meeting takes place under the following conditions:
   - A majority of the members for the specific IRB must be present (or connected via speakerphone/video) for all reviews/actions voted on at a convened meeting;
   - A passing vote must consist of a majority of members present (or connected via speakerphone/video) voting in favor of the motion;
   - An individual who is not listed on the active IRB membership roster may not vote with the IRB;
   - *Ex-officio* members of the IRB may not participate in the vote;
   - Ad hoc and cultural consultants may not participate in the vote;
   - At least one non-scientist member must always be present for the vote;
   - A physician must be present to vote on FDA regulated research.

3. If the outcome of the IRB vote is a "2" (approved pending submission of minor revisions), the IRB Chair or the individual chairing the meeting may review and approve the PI's response on behalf of the IRB under an expedited review procedure.

REFERENCES

21 CFR 56.108
21 CFR 56.109
45 CFR 46.107
45 CFR 46.108