

THE CONDUCT OF IRB MEETINGS

The Franklin University IRB conducts convened meetings in accordance with applicable federal requirements for full review (i.e., 45 CFR 46.108 and 38 CFR 16.108).

PROCEDURES

Preparation and Distribution of the Agenda

1. IRB staff develop, maintain, and revise the IRB meeting schedule, as appropriate. IRB staff coordinate meeting rooms and confirm the meeting dates.
2. IRB staff create an agenda approximately five calendar days before a meeting. IRB staff review the agenda for accuracy and completeness before making it available to members of the IRB.
3. If special circumstances exist, IRB staff prepare an addendum to the agenda and make it available to IRB members prior to the meeting.
4. IRB staff notify PIs of appointment times for initial full review protocols.
5. 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, IRB staff, or IRB members.

Quorum Requirements

1. A majority (e.g., IRB members = 7; majority = 4) of the IRB members must be present.
2. At least one member whose primary concerns are in non-scientific areas is present at the convened meeting.
3. Alternate members may attend in place of absent regular members in order to meet quorum requirements.
4. The IRB does not consider ad hoc and cultural consultants to establish a quorum.
5. 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 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 IRB staff may grant permission for the co-Investigator or knowledgeable party to attend in place of the PI. The IRB, IRB Chair, or IRB staff may also waive this attendance requirement.
3. For other types of review, IRB members, the IRB Chair, or IRB staff may also invite or require the PI to attend, when deemed appropriate.

4. IRB staff or the IRB Chair may grant permission for attendance by observers upon request. Faculty make requests on behalf of student observers to the IRB. Upon receipt of any request, IRB staff or the IRB Chair use discretion to grant permission for attendance to selected meetings by observers. IRB staff obtain a statement of confidentiality from observers who have permission to attend. The IRB 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.

6. IRB staff are responsible for preparing meeting minutes.

Tele/Videoconference Participation

1. The IRB may conduct convened meetings by tele/videoconference as long as IRB member(s) have received a copy of all of the documents under review at the meeting, a quorum as defined above is present, and discussion occurs in real time.

2. Such members count as part of the quorum and may vote. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference 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 IRB members must be present (or connected via tele/videoconference) for all reviews/actions voted on at a convened meeting;
- A passing vote must consist of a majority of members present (or connected via tele/videoconference) voting in favor of the motion;
- Ex-officio members of the IRB may not participate in the vote;
- Ad hoc and cultural consultants may not participate in the vote;
- The non-scientist member must always be present for a vote.

3. If the outcome of the IRB vote is 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.