

Series 407 Meetings of the Convened

Meetings of the Convened IRB from Series 407 of the Standard Operating Procedures

I. Meeting Scheduling

The Convened IRB will meet at least monthly during the Fall and Spring academic semesters, with greater frequency as deemed appropriate by the IRB Chair, Institutional Official, and HRP Director. The Convened IRB meets on an as-needed basis outside of the regular academic semester schedule. Meeting schedules are posted in advance on the IRB's website. If there are no items on the agenda one week prior to the scheduled meeting, the IRB Chair may cancel the meeting.

Meetings may occur virtually via video-conferencing software, in-person, or using a combination of those methods, provided that all members are able to participate in the discussion in real time and without any communication disadvantage relative to other methods of participation and meeting participants.

II. Preparing for the Meeting

At least one week prior to the scheduled meeting, the IRB Chair will coordinate with the HRP Director to set the agenda for the upcoming meeting based on the number of completed submissions requiring review by the Convened IRB. Items are placed on the agenda based on the submission date, as well as priority level. Items placed on the agenda are typically placed there in order of receipt (oldest first, newest last). Unanticipated Adverse Events, Unanticipated Problems, and Noncompliance items take priority for all meetings of the Convened IRB due to the direct impacts such issues are likely to have on participants. Initial protocol reviews generally require 45 minutes; Continuation Reviews and Amendments generally require 30 minutes. Noncompliance, Unanticipated Adverse Events, and Unanticipated Problems generally require an hour. The agenda should be reflective of these timeframes prior to being released to members of the IRB. Absent extenuating circumstances, the IRB should not review more than two initial reviews at a single meeting, to ensure that the workload is appropriate for the service faculty & community members are performing by virtue of their membership on the IRB.

Investigators can see whether their protocols have been assigned to an agenda by checking the Admin Notes & Files or Activity Log section of their Quali protocol, where assignment to a meeting will be reflected.

Materials for the upcoming meeting are distributed to IRB members at least five days prior to the meeting. Each agenda item will be assigned a Primary Reviewer, who will be responsible for presenting the review item to the Board. Prior to the meeting, each member in attendance must complete the IRB Member Checklist in Quali Protocols regarding each protocol under review. A member who fails to complete the IRB Member Checklist prior to the meeting will be considered absent for that discussion and cannot count toward a quorum or vote on the disposition of the protocol. Questions about materials, processes, or requirements should be directed to the IRB Chair and Vice Chair, and/or HRP Director. IRB members should leave their review comments in the protocol, so that the HRP Director can request clarification or discuss modifications with the research team prior to the meeting where the protocol will be formally reviewed.

III. Meeting Administration

Except when the Expedited or Limited IRB Review process is used, the IRB will review proposed human subjects research at a meeting of the Convened IRB where a quorum is present. Meetings shall be held in a space (physical or virtual) that is appropriate to permit considered discussion of proposal to conduct human subjects research.

A quorum is defined as more than half of full voting members serving on the IRB in attendance at a meeting, where the total number of members is taken from the Scientific Roster. No quorum can be had without the following individuals present, regardless of the number of members otherwise in attendance:

- The IRB Chair (or Vice Chair)
- An unaffiliated member
- A scientist
- A non-scientist, and
- A Prisoner's Advocate, when the agenda includes items where incarcerated persons are participants other than incidentally. The Prisoner's Advocate does not count as a member for the purpose of a quorum count when the agenda does not include items where incarcerated persons are participants other than incidentally.

The meeting agenda and/or minutes for each meeting of the Convened IRB shall include the following items:

1. Call to order & Meeting time/location
2. Establishment of quorum & statement that no votes may be taken unless quorum is intact
3. Members in attendance & their affiliations as pertains to establishment of quorum
4. That approvals require a majority vote of the members present at the meeting
5. Conflict of interest disclosures
6. Late arrivals and early departures of members, and if quorum is impacted, an indication of when quorum was established once more.
7. Others in attendance and their roles (e.g. consultant, study staff, auditor, etc.)
8. The items up for review

The IRB Chair shall call a meeting to order after quorum has been confirmed. It is the responsibility of the HRP Staff Assistant to track quorum, attendance, and departures and alert the IRB Chair should any pauses or adjournments be necessary due to quorum requirements.

The Convened IRB operates using Roberts Rules of Order. A member wishing to take action shall make a motion, and another member shall second that motion. Upon receipt of a second, the motion is debated and then voted upon. Votes for, votes against, and members abstaining shall be recorded during the meeting by the HRP Staff Assistant. Motions are approved when they receive a majority vote from the members in attendance and while quorum is intact. Motions to adjourn are accomplished either by this process, or by assumption of motion by the Chair.

IV. Conflicts of Interest

No IRB member, consultant, study staff, or other individual with a conflict of interest as defined in the Board Member Agreement and/or the Office of Research Integrity and Compliance shall participate in the review process for any item under consideration by the Convened IRB, except as necessary to provide information to the IRB. Any person having a conflict of interest must recuse themselves from voting, and should excuse themselves from the meeting during the discussion and vote of that item if they are not actively providing information to members of the IRB.

Before any item requiring a vote is taken up in the meeting, IRB members will be reminded by the IRB Chair to disclose any conflicts of interest. If a conflict of interest is disclosed, the minutes of the meeting shall reflect that disclosure. The HRP Director or analysts must inform the IRB Chair of any conflicts of interest they might have or be aware of during this time.