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1. PURPOSE

1.1. This policy establishes the process for reviewing research protocols requiring full board or convened IRB review.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Federally funded or supported research protocols not meeting the criteria for expedited review and more than minimal risk, will be reviewed by the convened IRB.


3.2. For each convened IRB meeting, all IRB members will receive a copy of all new protocols scheduled for review, along with any supporting documents (including, but not limited to, research tools, informed consent documents, and recruitment materials). All IRB members scheduled to attend receive a complete agenda packet. If any alternate members are scheduled to attend the meeting, the alternate will receive the complete agenda packet. Alternate members only receive agenda packets for convened meetings for which they are scheduled to attend.

3.3. For new protocols reviewed at convened meetings, at least one voting member of the IRB is assigned to be the primary reviewer. The IRB staff assigns IRB members as primary reviewers based on the nature of the research itself and the expertise and experience of the IRB member, when possible.

3.4. All Principal Investigators are invited to attend the convened IRB meeting in which their full-review protocol is scheduled for review. Attendance at the meeting allows a researcher to discuss his/her project with the IRB, thus enabling the IRB to understand the research procedures and to help the researcher comply with the applicable regulations. PIs may be faculty or student researchers. To balance the need for compliance, efficiency, and educational benefit, attendance requirements differ for faculty and student researchers as set forth below.

Faculty Principal Investigators

3.4.1. A faculty PI who has not previously submitted a full-review protocol and attended a convened IRB meeting at Marquette University is strongly advised to attend (unless the IRB determines otherwise) the meeting in which his or her full-review protocol will be reviewed. This allows IRB members to effectively discuss and evaluate with the PI research that presents more than

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minimal risk. Non-attendance may delay approval and commencement of the research. The IRB convenes monthly and requested changes or clarifications may also require full review. In some cases, the need for substantial clarification may result in denial of IRB approval, in which case a resubmission for full review is required.

3.4.2. For faculty PIs who have previously submitted a full-review protocol and attended a convened IRB meeting at Marquette University, attendance is optional, unless the IRB determines otherwise.

3.4.3. A faculty PI may invite up to 2 members of his or her research team to attend the IRB meeting in which the PI's protocol will be reviewed, for a total of 3 attendees.

3.4.4. Attendance for amendments, yearly continuing reviews, and 3-year reviews requiring full review is optional, unless the IRB determines otherwise.


Student Principal Investigators

3.4.5. A student PI who has a full-review protocol scheduled for review by the convened IRB must attend the meeting with his or her faculty advisor or another faculty member who is familiar with the research. This provides the greatest benefit to the student researcher, as well as to the student's advisor and the IRB members.

3.4.6. A student PI may not be admitted into the meeting until his or her advisor/faculty member arrives. If the advisor/faculty member does not arrive before the meeting concludes, the student's protocol may be tabled until the next meeting.

3.4.7. A student PI and his/her advisor may invite 1 additional member of the research team to attend the IRB meeting in which the PI's protocol will be reviewed, for a total of 3 attendees. Should the PI require additional attendees, the PI must contact the Office of Research Compliance.

3.4.8. Attendance for amendments, yearly continuing reviews, and 3-year reviews requiring full review is optional, unless the IRB determines otherwise. A student PI may attend these reviews with or without his or her faculty advisor.

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- 3.5. The investigator, if in attendance at the convened meeting, is asked to provide a brief description of the research project, focusing on the involvement of human subjects. The IRB then has the opportunity to ask questions and seek clarification from the investigator. The investigator is excused prior to the IRB's discussion and vote. If the investigator is not present, the primary reviewer is expected to provide a description of the research.
- 3.6. After sufficient discussion, the members make a determination on each research protocol. If the IRB needs additional information, the protocol is incomplete, additional time is needed for discussion, or the IRB needs to delay voting for any other reason, the protocol may be tabled. An IRB member, typically the primary reviewer, must initiate a motion prior to a vote. The motion must be seconded by a second voting IRB member prior to the vote. When a motion is not seconded, it does not go forward to a vote. Any motion that is seconded must go forward for a vote unless the person who made the motion withdraws it. If a motion does not pass, another motion may be made for consideration.
- 3.7. If the IRB proceeds with a vote, the following determinations may be made:
1. Approved: Approve as submitted.
 2. Approved with Conditions: The protocol is approved pending fulfillment of contingencies. Contingencies are reviewed and approved by the primary reviewer(s) or if determined, IRB staff, and do not require review by the convened IRB. Investigators have 6 months from the date of initial review to meet contingencies. If contingencies are not met within that timeframe, the protocol will be administratively withdrawn by the IRB. Investigators may request an extension if extenuating circumstances exist.
 3. Disapproved: The research protocol cannot be approved as proposed.
- 3.8. The decisions will be based on the votes of the majority (more than 50%) of the voting members present at a full board IRB meeting.
- 3.9. Any IRB member may make a motion on a topic not listed on the agenda. The IRB may choose to vote on items not previously listed on the agenda.