1. PURPOSE
   1.1. This policy establishes the procedures for convened IRB meetings.

2. REVISIONS FROM PREVIOUS VERSION
   2.1. None

3. POLICY
   3.1. IRB Meeting: IRB members convene regularly to fulfill their mandate to oversee research involving human subjects at MU. The IRB generally meets once per month, but may add additional meetings if the IRB determines they are necessary. Alternatively, a monthly meeting may be cancelled. The IRB meeting schedule is available on the ORC web site and is subject to change.

   The IRB has an agenda for the meetings. The agenda includes all research protocols awaiting action by the IRB and an administrative report of all research that has been approved by experienced reviewers through exempt or expedited review procedures.

   A meeting packet is provided to IRB members approximately one week before the meeting to allow sufficient time to review the research protocols. The meeting packet contains a copy of the IRB agenda, each protocol up for review, with any supporting documents including research tools, informed consent documents, assent documents, and recruiting materials.

   3.2. IRB Quorum: A quorum is defined as greater than 50% of the voting membership including attendance of at least one non-scientist.

   The approval of a research protocol requires the vote of a simple majority (greater than 50%) of the voting members present at the meeting.

   Voting members may attend full board meetings of the IRB by teleconference or videoconference, if they have been provided a copy of all of the items for review in advance of the meeting, and the equipment permits meaningful participation in discussion and voting. There are no provisions for any other kind of proxy or written vote, since IRB members must be in attendance to vote. However, IRB members may submit written comments or questions in relation to the protocols or other issues under review, including in advance of a convened full-board review.

3.3. Conflicts of Interest: The IRB Chair will remind those in attendance the importance of maintaining confidentiality and disclosing any conflicts of interest. IRB members must disclose any known potential conflicts of interest to the Chair at the start of the IRB meeting or prior to the discussion and vote the protocol they have a conflict with. IRB members may not participate in the voting on research protocols in which they may have conflicting interests. Whenever research in which a member of the IRB has an apparent conflict of interest is being reviewed, that member may be asked to recuse him or herself from the meeting (leave the room) for the duration of the discussion and review of that research protocol if the member's presence could create a bias.

3.4. IRB Meeting Minutes: The IRB staff prepares minutes of each meeting of the IRB, documenting the Committee's review of research protocols, policy discussions, and continuing education. The minutes are recorded in sufficient detail and include the following:

1. IRB Member attendance and the presence of any invited investigators or guests.
2. IRB committee acknowledgement of administrative actions by the IRB Chair or designated representative taken for Expedited and Exempt protocols.
3. Summary of the discussion, in particular discussion of required modifications for each research protocol reviewed.
4. Decisions reached on each research protocol reviewed.
5. Votes on the decisions, including a tally of votes for, against, abstaining and total present for the vote. Recusal of members due to conflicting interests is also documented.
6. Reasons for requiring modifications to secure approval of a research protocol, for disapproving a research protocol, or suspending or terminating a research protocol.
7. If a waiver or alteration of informed consent or a waiver of documentation of informed consent is requested, the specific findings supporting the IRB's determination.
8. The level of risk involved in the research as indicated by the level of review the research receives.
9. The review frequency for the next continuing review. If no shorter review frequency is noted, the protocol will undergo review annually.

A copy of the minutes for the previous meeting is provided to the IRB members for review in the meeting packet, to give members an opportunity to request clarifications or suggest changes to the minutes. Suggested modifications to the minutes are discussed at a full board meeting and agreed to by consensus.

3.5. Investigator Attendance: The IRB may request the attendance of investigators at an IRB meeting so that IRB members may ask questions and clarify information. Researchers' team members may, and often do, also attend IRB meetings.

3.6. IRB Communication of Meeting Findings and Actions to the Investigator and the Institution: Communication of IRB requests for revisions and modifications are submitted to the PI by e-mail. Communication of IRB approval is done officially in writing with a copy of the correspondence is sent to the PI by e mail.

While the IRB will communicate with PIs as necessary, it is ultimately up to the PI to ensure that all requirements have been met in a timely fashion and that human subject research is only conducted after the IRB has reviewed and approved the protocol. Additionally, the PI is responsible for ensuring that the only human subject research conducted is that described in the IRB approved protocol.