The Biomedical and Health Institutional Review Board (BIRB), the Community Research Institutional Review Board (CRIRB) and the Social Science / Behavioral / Education Institutional Review Board (SIRB) each meet once a month and may schedule other meetings on an emergency basis. Emergency meetings may include teleconferencing. Meeting dates are posted on the Human Research Protection Program (HRPP) website: BIRB and SIRB meetings are held on campus. When necessary, videoconferencing or teleconferencing is utilized for some members. CRIRB meetings are held contemporaneously using the web and teleconferencing. All requirements, as outlined in this policy, must be followed. If no business is necessary on any particular month that month's meeting may be cancelled.

**Chair and Vice Chair Meeting Roles & Responsibilities**
The Institutional Review Board (IRB) chair shall chair and vote at the appropriate IRB meetings. A vice chair shall perform the chair duties when the chair is unavailable. See HRPP Manual 5-1 “IRB Chairs” for a complete list of chair duties.

**Deadline**
The deadline for distribution of agenda materials to all IRB members is at least ten days before the meeting date. In special circumstances and in consultation with the IRB chair, a research study may be added in the week preceding the meeting. If a study is added, the IRB staff will make special efforts to provide the materials to all IRB members to review the information.

Investigator submission deadlines for full review initial applications, full review renewals, and non-minor revisions will be posted to the HRPP website. If complete full review initial applications, full review renewals and non-minor revisions are received with all appropriate supporting documents by the submission deadline they will be placed on the meeting agenda for discussion. However, studies that have substantial IRB primary reviewer comments which have not been sufficiently addressed by the investigator prior to the meeting may be tabled by the IRB. Applications received after the posted deadline date will be included in the following month’s agenda with limited exceptions.
Quorum
A quorum is constituted when a majority of IRB members is present including at least one non-scientific member and one physician member (whenever studies involving investigational drugs or devices are on the agenda). A quorum of members must be present for a meeting to take place.

The IRB administrator determines anticipated attendance the week preceding the meeting. The IRB administrator will confirm quorum prior to the start of the meeting. If quorum is not met, actions or votes may not be taken. Throughout the meeting the IRB administrator checks and confirms quorum. The attendance, arrival, and departure of members are noted by the IRB administrator and in the minutes to assure that no action is taken unless a quorum is present. If attendance falls below quorum during the meeting, the IRB administrator will announce that quorum has been lost and no further actions can be taken.

The IRB administrator, in conjunction with the IRB chair, will assure appropriate representative capacities are present at the meeting. If research involves prisoners, the IRB administrator will assure that the prisoner representative is present. Research involving prisoners that requires full review can only be reviewed if the prisoner representative is present at the convened IRB meeting. If the IRB reviews research that involves categories of subjects vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such subjects must be present. If there is not at least one person on the IRB with appropriate scientific or scholarly expertise to conduct an in-depth review of the study, the IRB will defer to another meeting, another IRB, or obtain other consultation. See HRPP Manual 5-4 “Additional Expertise” for policies and procedures on obtaining additional expertise.

The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. See HRPP Manual 5-3 “IRB Membership” for IRB composition requirements. MSU considers the presence of non-affiliated representation at convened IRB meetings to reflect community attitudes an important element of the IRB’s diversity. Therefore, frequent absence of all non-affiliated members is not acceptable. The IRB administrator will monitor attendance of non-affiliated members to assure there are not frequent absences and that appropriate representative capacities are present at the meeting.

Information Provided to IRB Members
A preliminary agenda detailing items to be discussed at the meeting (including, new full review studies, full review renewals, non-minor revisions, noncompliance, unanticipated problems involving risks to subjects or others, information items, and discussion items), and pre-meeting materials are available to all IRB members, including alternates anticipated to attend the meeting, typically a minimum of ten days prior to the scheduled meeting. The agenda also includes all studies that were approved via an expedited and exempt review process since the last convened IRB meeting. The materials are
accessible via the MSU IRB online system. Materials unavailable through the MSU IRB
online system will be distributed via ANGEL (online learning management system).

Materials made available include:
- Draft of minutes from the previous convened IRB meeting
- Preliminary agenda
- Studies requiring full review received by the submission deadline (initial full
  review applications, full review renewals, non-minor revisions)
- Items for notification (i.e., expedited, exempt)

See HRPP Manual 8-3 “Full Board Review Procedure” for specific materials provided
for review.

At the meeting, the following materials are available to each IRB member via a laptop
computer:
- Agenda
- Initial full review applications: lead review summary, initial application, consent
  form(s), recruitment material, primary reviewer(s) comment(s)
- Full review renewals: renewal review sheet, renewal application, consent form(s),
  study progress report (if applicable)
- Non-minor revisions: revision review sheet, revision application, revised and/or
  modified material(s)
- Information items
- Discussion items

Reference documents for approval criteria, such as the criteria for approval, informed
consent requirements, and requirements for research involving subpart B, C, or D are
also available to IRB members during the meeting via a laptop computer. The files of all
studies under review by the convened IRB are available for review upon request.

**Actions Taken and Communication of Such Actions**

Applications undergoing expedited review may be approved between convened IRB
meetings. Applications undergoing exempt review may be approved and/or determined
to be exempt between convened IRB meetings. These studies will be listed on the
meeting agenda and may be discussed at the request of any member present or by
request of an IRB member prior to the meeting. No vote or action is required for these
items by the convened IRB.

Applications undergoing full review must be discussed and voted on by IRB members at
a convened IRB meeting to be approved. The lead reviewer, IRB chair, or other
designated member will summarize the review and questions raised during the primary
review. Members at the convened IRB meeting may ask questions or provide
discussion about each particular study. Other actions requiring a vote at IRB meetings
include full review renewals, non-minor revisions, and discussion items (e.g.,
noncompliance, unanticipated problems).
Approval will be granted when a majority of members present vote for approval. A majority of members present may also vote for conditional approval, tabling, or disapproval of research studies.

There is no limit on the number of full review studies which can be reviewed at each meeting. There are also no limits to the number of items (e.g. applications, noncompliance, unanticipated problems, other items) placed on the agenda. Discussion and review of each study under consideration by the convened IRB must be substantive and meaningful. However, if quorum is lost during the meeting, the meeting will stop immediately and no further action will be taken until quorum is restored. See HRPP Manual 8-3 “Full Review” for a description of the above mentioned actions and how they are communicated to investigators.

Noncompliance and Suspension/Termination
See HRPP Manual 9-2 “Noncompliance,” 9-3 “Termination or Suspension of Research,” and 4-8 “Reporting Policy” for policies and procedures on these actions, including materials reviewed by the IRB and communication of actions.

Criteria for Approval
See HRPP Manual 6-1 “Criteria for Institutional Review Board Approval of Research” for a complete list of criteria for IRB approval of research.

Voting
Individuals listed on the roster are voting members. After each study is discussed, the IRB chair will call for a vote to determine if the study is approved, conditionally approved, tabled, or disapproved. Members are asked to vote “for,” “against,” or to “abstain” regarding the study. The majority vote determines the outcome. The IRB minutes shall reflect the outcome of each vote.

Federal regulations (e.g., 45 CFR 46.107(e), 21 CFR 56.107(e)) prohibit a member of the IRB from participating in the initial or continuing review of any study in which the member has a conflicting interest, except to provide information at the IRB’s request. IRB members may not vote on studies if they have a conflict of interest and must leave the room during discussion and voting of such studies. See HRPP Manual 10-1 “Conflict of Interest” for policies and procedures on IRB member conflict of interest. The IRB chair will remind IRB members of this requirement at the beginning of each meeting.

Confidentiality
MSU IRBs are confidential review bodies. University members, community members, and consultants hold the contents of meetings in confidence to the maximum extent allowed by law and may not use any information gleaned from meetings for their own gain.

Meeting Minutes
The minutes of the IRB meeting shall reflect the conduct sufficient to document, at a minimum:
• Attendance (including when an alternate member replaces a primary member)
• Actions taken by the IRB
• Separate deliberation for each action taken and vote on each research study (including the number of members voting for, against, and abstaining)
• Approval period for initial and continuing review
• Basis for requiring changes in or disapproving research
• Written summary of the discussion and resolution of controverted issues regarding research studies
• Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document
• Determinations required by the regulations and study specific information justifying each determination (e.g., research involving pregnant women, fetuses or neonates, children, prisoners, waiver of consent, alteration of consent, or waiver of documentation of consent)
• Rationale for significant risk / non-significant risk device determinations, when appropriate
• Arrival and departure of members during the convened IRB meeting
• Departure of members because of a conflict of interest, specifically documenting the name of the IRB member who left the meeting because of a conflict of interest along with the fact the conflict of interest is the reason for leaving

The minutes may also contain additional information that reflects the length of meeting, decisions on studies made outside the IRB meeting, actions on other items of business, and a listing of information items.

If a consultant was solicited to review a study pursuant to HRPP Manual 5-4 “Additional Expertise” and attends the meeting and speaks, the information will be recorded in the minutes. However, the consultant cannot vote if she/he is not a member of the IRB. See HRPP Manual 5-4 “Additional Expertise.”

A standard form will be used to document the discussion and actions and will be incorporated into the minutes. The minutes will be distributed to IRB members to review prior to the subsequent meeting.

After the minutes have been reviewed by the IRB, a copy is sent to the Institutional Official or his/her designate and the original is placed in the agenda material binder.