If an activity requires review by a Michigan State University (MSU) Institutional Review Board (IRB), research may not be conducted until the IRB has reviewed and approved the research study and the researchers have received electronic notification to print the approval letter and IRB-approved consent form(s) (if applicable). See the Human Research Protection Program (HRPP) Manual 4-3 “Determination of Human Subject Research” for the policies and procedures on when a research study must be submitted to the IRB. See HRPP Manual 8-1 “Exemption” for policies and procedures on the submission and review of exempt research.

To apply for approval of a research study, the principal investigator (PI) must submit an initial application for expedited or full board review to the IRB.

**Materials Required for Submission**
To evaluate the research study, the IRB members must have the initial application and all applicable supporting documents. The following supporting documents must be included whenever applicable:

- Instrument(s) or measures (e.g. survey(s), interview questions, questionnaire(s), case report(s), protocol)
- Consent form(s) or script(s) for verbal consent (unless requesting waiver of consent)
- Assent form(s)
- Recruitment material(s), including advertisement(s)
- Contract or grant application and MSU Office of Sponsored Programs (OSP) number for externally funded research
- Debriefing form(s)
- Translation of instrument(s) and consent(s) provided to non-English speaking subjects
- Health Insurance Portability and Accountability Act authorization form(s)
- Investigator brochure(s)
- U.S. Department of Health and Human Services (DHHS) approved sample informed consent(s) and complete DHHS approved protocol(s) for DHHS sponsored multi-center clinical trials
- If submitted to other IRB(s), that institution(s) approval letter(s)
• Package insert(s) if using a U.S. Food and Drug Administration approved drug/device/diagnostic test
• U.S. Food and Drug Administration (FDA) form 3454 or 3455
• FDA form 1572
• Curriculum vitae when research is more than minimum risk
• Any other pertinent documents related to the proposed research study

**Mechanism(s) for Submission**
For research studies submitted to the MSU IRB, the initial application must be completed and submitted using the MSU IRB online system. The initial application must be completed in full; all questions must be completed. The MSU IRB online system will not allow submission of an incomplete application. An approval letter will not be released until the IRB office is in receipt of confirmation from the PI through which the PI accepts responsibility for the research study.

**Submission Processing**
The IRB staff assigns the initial application an IRB number. The IRB staff checks for completeness (e.g., appropriate documents attached) and appropriate level and category for review. Incomplete applications will be returned. IRB staff verifies current training for researchers listed on the research study. IRB staff will notify the PI of any individuals without current training and those individuals must have current training before the approval letter can be issued.

**Change in Review Level**
Investigators indicate on the application which level of review (expedited or full board) and category (for expedited) they believe the research study falls into, but the IRB staff, chair, or members may change the category if the selection is not appropriate. See HRPP Manual 8 “Types of IRB Review” for policies and procedures related to change in review level and/or category.

**Materials Provided to IRB Members**
Assigned reviewer(s) may access the initial application and supporting documents associated with the research study (e.g., consent, instruments) via the MSU IRB online system. Any document(s) not accessible online will be provided to the reviewer(s).

**How Review is Conducted**
For review procedures, see HRPP Manual 8-2 “Expedited Review Procedure” or 8-3 “Full Board Review.”

**IRB Member Considerations**
When reviewing initial applications, the criteria for IRB approval must be met to approve or recommend approval of the application. The IRB member(s) should utilize HRPP Manual 6 “IRB Evaluation Criteria.”

In addition, IRB members should utilize the additional criteria for approval if research subjects include vulnerable populations such as pregnant women, human fetuses,
Additional Considerations
With limited exceptions specified in HRPP Manual 8-8 “Demonstration Projects,” an IRB may not approve a research study for more than one year. Typically, the approval period is 364 days. However, in studies where any of the following conditions are likely to prevail, the IRB may require review more often than annually:

- Phase I trials
- Clinical studies where risks to health are considered life threatening
- Behavioral studies where stress to subjects could threaten health
- Studies where data monitoring and security issues may warrant more frequent review
- Others as the IRB sees fit

If the IRB chair, member, or staff recommends that a protocol requires review more often than annually, it will be referred to the convened IRB. When the IRB determines review is needed more often than annually, that determination will be communicated to the researchers in writing and documented in the minutes.