Michigan State University (MSU) may rely on a commercial Institutional Review Board (IRB) to oversee the management and review of certain protocols when specified criteria are met. When entering into such a relationship, MSU will evaluate whether the commercial IRB has equivalent human subject protections in place. Such evaluation will include consideration of whether the commercial IRB is accredited. To assure accreditation standards are fulfilled, MSU will typically only rely on commercial IRBs that have accreditation from the Association for the Accreditation of Human Research Protection Programs. A fully executed agreement is required before MSU may rely on a commercial IRB for review.

The principal investigator (PI) is responsible for assuring that the commercial IRB fees are paid for by the sponsor. If the sponsor fails to pay the IRB fees within the required time frame, the PI's department will be responsible for the fees.

The PI will be required to submit a request to the MSU IRB office before a protocol can be submitted to the commercial IRB. The MSU IRB staff will evaluate the application to determine if the appropriate criteria are met. A fee will be charged for each request to use a commercial IRB to off-set administrative costs associated with the review process and interactions with the commercial IRB. See the Human Research Protection Program Manual (HRPP) 5-8 “Institutional Review Board Fees” for requirements.

A research study will be considered for review by a commercial IRB if the following conditions are met:

1. The project is a study that involves human subjects and is designed to evaluate prospectively the safety and/or effectiveness of new drugs or devices or behavioral intervention.
2. The protocol for the research study was designed and written by the sponsor.
3. The sponsor holds all INDs/IDEs for the protocol.
4. The only sponsor of the research is a for-profit entity/company.
5. The protocol is a national multi-site protocol where the protocol has already been reviewed or approved at other sites.
6. The MSU investigator has not previously submitted the study to a MSU IRB [only new research studies will be eligible for commercial IRB review. No transfer of research studies already submitted to a MSU IRB will be allowed].
A research study will not be considered for review by a commercial IRB if the study involves, including but not limited to, the following types of research:

1. Xenotransplantation
2. Embryonic stem cells
3. Phase I clinical trials
4. Review and approval by other committees – e.g., studies that involve recombinant DNA, radioisotopes, biorepositories
5. Any research funds from a federal or other not-for-profit funding source

MSU retains final authority to determine whether a research study can be submitted to a commercial IRB for IRB review.

The MSU IRB staff evaluates the request to determine if the criteria are met for commercial IRB review and to assure that the research study does not involve research that would not qualify for review by the commercial IRB. If the research study qualifies for review, the IRB staff will notify the investigator and the commercial IRB as defined by the agreement.

The PI is responsible for completing and submitting the commercial IRB application to the commercial IRB and providing a copy to the MSU IRB. The protocol submission will be assigned an IRB number and tracked within the MSU IRB system.

Communication between the commercial IRB and the MSU IRB staff and reporting notifications will occur as defined by the agreement and in compliance with HRPP Manual 4-8 "Reporting Policy."