All significant financial interests and other opportunities for tangible personal benefit related to the design, review, conduct or reporting of human research projects that could, or appear to, affect the rights and welfare of human participants or the objectivity of the research results must be disclosed in accordance with the procedure established by the Faculty Conflict of Interest Officer (FCOIO) and the HRPP. Review of reported conflict situations must consider the associated risk to human participants and the integrity of the research findings. This includes conflict of interest situations for all projects regardless of the funding source, including non-sponsored research, for all Institutional Review Board (IRB) members, HRPP staff, investigators, research staff, or consultants serving in any capacity. Organizational conflict of interest situations must also be considered for the same reasons. The keys to managing conflicts are disclosure and transparency.

MSU faculty and academic staff must report conflicts of interest according to MSU policies. See MSU Faculty Handbook, IV. Academic Human Resources Policies: Conflicts of Interest, Faculty / Academic Staff and Human Research Protections Program (HRPP) Manual 10-1 “Conflict of Interest.”

No member of the IRB (or HRPP staff) shall serve as a reviewer, or contribute to the review, of a proposal for which he or she has a conflict of interest. Such conflicts are satisfactorily managed by the IRB (or HRPP staff) member’s recusal from participating in, or contributing to, the review. Individuals who are responsible for business development cannot serve as a member on the IRB or carry out day to day operations of the IRB review process.

**Definitions**

**Individual Conflict of Interest (COI)**
A conflict of interest exists when an individual’s financial interests or other opportunities for tangible personal benefit may compromise or appear to compromise the independence of judgment with which the individual performs his/her responsibilities. The individual does not have to do anything improper to have a conflict of interest; it could also be strictly situational or present an appearance of a conflict.
An individual’s financial interests or other opportunities for tangible benefit must be judged not only by his/her personal holdings, but also on an aggregate basis with members of his/her immediate family (spouse, domestic partner, dependent children, and other dependents) and any legal entity that one or more of them owns or controls.

**IRB Member or HRPP Staff Conflict of Interest** includes, but is not limited to, conflict situations related to review of initial applications, renewals, revisions, unanticipated problems involving risk to subjects or others, non-compliance investigations, or suspension/termination decisions. The following examples are illustrative and not exhaustive. Other situations that may create conflicts of interest must be disclosed by IRB members or staff.

Conflict situations include, but are not limited to reviewing or managing a project involving:

- An IRB/HRPP-staff member’s immediate family (spouse, domestic partner, dependent children, and other) or relatives as defined by the Conflict of Interest in Employment Policy, or persons with whom there is a consensual amorous or sexual relationship.
- A graduate student for which the IRB member serves on the thesis or dissertation committee.
- An IRB member who serves as an investigator or provides support on a project being reviewed.
- Funding by a company or other entity in which the IRB/HRPP-staff member holds a significant financial interest or by one of its competitors.
- Another MSU faculty member who has a financial interest in a company or other entity, or one of its competitors, in which the IRB member conducting the evaluation also holds a significant financial interest.
- Funding by, or that affects, a company that has provided or offers gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities to an IRB/HRPP-staff member.

The judgment about what to report as a conflict of interest lies first and foremost with the IRB (or staff) member. Holding an appointment in the same academic unit as the person whose project is being reviewed, does not, without more, constitute a conflict of interest.

**Financial Interest:** A financial interest is anything of monetary value, whether or not the value is ascertainable, including but not limited to:

- Payments for services such as consulting fees, salary, honoraria, or commissions.
- Equity interests like stock and stock options.
- Other ownership interests, like being a partner in a partnership or operating an unincorporated business.
- Beneficial interests, *i.e.*, being the beneficiary of a trust or estate or a trustee of a trust or estate benefitting a family member.
- Indebtedness.
- Intellectual property rights, like the right to receive royalties or licensing fees as a result of a patent or copyright.
• Gifts of goods, property, or services, like airline tickets, resort or hotel accommodations, or other recreational or personal amenities.
• Service on a corporate board or as a corporate officer, or on the scientific advisory board of a company, is a financial interest in that entity, if payment is received for the service. But, even unpaid service as a corporate director or officer or as a corporate advisor can be an opportunity for tangible personal benefit that can form the basis for a conflict of interest.

A financial interest can arise from any kind of legal entity including but not limited to a corporation or limited liability company; a partnership, limited partnership, or joint venture; a trust or estate; a firm, franchise, “dba” (doing business as), sole proprietorship, unincorporated association, or other business.

**Significant Financial Interest:** Significant financial interests are defined under the Faculty / Academic Staff Conflict of Interest Policy and must be reported.

A significant financial interest includes, but is not limited to, a financial interest in the sponsor, product, or service being tested, or in a competitor of the sponsor or product or service being tested.

The following are deemed to create a “significant financial interest”:
• Income or receipt of payments of any kind totaling more than $5,000 over the last calendar year from a single entity;
• Ownership interests in a single entity of greater than one percent (1%) or of an amount exceeding $5,000;
• Intellectual property rights or licenses with an established fair market value exceeding $5,000 or which generate income of any value from other than MSU (including royalties from other domestic universities);
• Unvalued stock options or other options for ownership in a privately held company of any value;
• Paid or unpaid service on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner of, an entity;
• Serving as a trustee for a trust or estate, or having a beneficial interest in a trust or estate, whose value exceeds $5,000;
• Indebtedness to or from a single entity in an amount exceeding $5,000;
• Receipt of gifts of goods, property, or services, like transportation, resort or hotel accommodations, or other recreational or personal amenities;
• Other opportunity for tangible personal benefit.

The following financial interests are excluded from consideration and do not need to be reported:
• MSU salary, remuneration by MSU, or other payments at MSU’s behest (including from an MSU-approved practice plan);
• Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels paid by:
o Federal, state, or local U.S. government agencies;
o U.S. institutions of higher education;
o U.S. academic teaching hospitals and medical centers;
o U.S. research institutes affiliated with an institution of higher education;

- Financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over whose management and investments neither the individual nor any immediate family member has control;
- Indebtedness from a bank, credit union, or other commercial lender.

**Organizational Conflict of Interest (OCOI)**

An “Organizational Conflict of Interest” exists for research involving human subjects when MSU’s financial interests, or those of its “institutional leaders”, may affect or reasonably appear to affect institutional processes with which the IRB or other offices responsible for supporting Human Research Protection efforts carry out their responsibilities in reviewing a proposed human research protocol and/or managing a human research project once it has been approved by the IRB.

Financial interests creating an organizational conflict arise in research on drugs, devices, biologics, or other questions of potential value from:

- protected intellectual property, licenses for commercialization of patented intellectual property, or receipt of royalties or other fees from licensed intellectual property, and/or
- gifts exceeding $50,000 from organizations or individuals that would stand to benefit, or reasonably expect to benefit, as a result of the research.

“Institutional Leaders” means Deans, Separately Reporting Directors, and Executive Managers who have direct authority for faculty appointments, allocation of institutional resources, assurance of institutional compliance, application of disciplinary standards, and other similar administrative tasks. Obligations regarding conflicts of interest (See Faculty & Academic Staff Policies & Procedures: Standards of Official Conduct for Deans, Separately Reporting Directors, and Executive Managers) related to institutional responsibilities address the following:

- Use of confidential information,
- Outside influence through personal gifts,
- Use of authority, University resources,
- Conflicting or incompatible service, and
- Competition with the University.

MSU recognizes and supports the principle that individual scholars are free to select the subject of their research and to seek support for their research from any source, under provisions that are stated in the Faculty Handbook, Faculty Rights and Responsibilities (See Section IV. Academic Human Resources Policies). Consideration of organizational conflicts of interests for research involving human subjects is intended to address circumstances having the potential to adversely impact a faculty member’s research if it is not managed appropriately or eliminated.
**Procedures**

**Investigator and Research Staff COI**

Investigators, research staff, and consultants (including agents of MSU, or others not employed by MSU) are required to report significant financial interests or other opportunities for tangible personal benefit when they relate to or could be affected by the proposed project. The IRB also requires the following situations to be reported at the time of the initial application for IRB review:

- Any ownership interest, stock options, or other ownership interest related to the research where there is an arrangement entered into where the value of the ownership interests could be affected by the outcome of the research
- Any compensation related to the research where there is an arrangement entered into where the amount of compensation would be affected by the outcome of the research

In addition, individuals responsible for the design, conduct, or reporting of more than minimal risk research must submit disclosures as required by the COI office and update such disclosures annually.

If a potential conflicting interest arises after IRB approval, the individual with the interest must promptly report its details as required by the Faculty Conflict of Interest Policy, notify the IRB staff and/or IRB chair, submit an amendment (revision) to the approved protocol addressing the conflicting interest, and include a revised consent form including a statement addressing any potential conflict of interest. Additional requirements of the MSU Faculty COI Policy should be followed by MSU faculty and academic staff.

When a person discloses interest in an entity, the COI office obtains details of the situation. The MSU Faculty Conflict of Interest Officer assists in making a determination of whether the disclosed interest constitutes a financial conflict of interest in accordance with the MSU Faculty / Academic Staff Conflict of Interest Policy and related procedures. This determination is communicated to the IRB.

When a conflict is identified, the conflict can often be managed through a written Management Plan. The management plan is developed according to the MSU Faculty / Academic Staff Conflict of Interest Policy. The FCOIO works with the IRB Chair or IRB staff to communicate with the IRB regarding determinations and recommendations provided by the FCOIO. A recommendation will be provided to the IRB on whether the financial interest has the potential to affect the rights and welfare of human subjects participating in the project and whether management alone is suitable or some other resolution is required.

The IRB will consider whether conflict of interest recommendations are satisfactory or whether a conflict of interest will affect the rights and welfare of the subjects participating in the project. The evaluation criteria do not vary by funding agency or regulatory oversight. Evaluation considerations may include whether disclosure in the consent form is adequate to protect human subjects or if additional safeguards are needed. If the IRB
determines that a conflict of interest could affect the rights and welfare of participants or the integrity of the research findings, then the conflict of interest must be eliminated or a management plan must be implemented so that the rights and welfare of participants are not affected by the interest. The chair of the IRB will notify the HRPP Director and the FCOIO of such determinations, and the IRB chair will work with the FCOIO accordingly.

The IRB typically requires a statement in the informed consent that discloses the nature of the significant financial interest or the financial conflict of interest. If a statement is not included in the consent, the investigator must explain why such a statement is not necessary for the protection of human subjects.

Organizational Conflict of Interest
Annually, all institutional leaders are required to report individual financial interests with organizations that do business, or intend to do business, with the University and to affirm that s/he has complied with the Standards of Official Conduct Policy during the previous year and will comply with the Standards of Official Conduct Policy during the next year. Disclosure of interest in an entity will be forwarded to the Institutional Official (IO) for determining if any of the reported financial interests might significantly and directly influence or be influenced by human subject research project(s). When such relationships are deemed to exist, the IO will communicate this information to the HRPP Director and the IRB Chair.

When an organizational conflict of interest exists, the IO will work closely with the FCOIO and the IRB chair to determine if the conflict could affect the rights and welfare of subjects participating in the project, the integrity of data collected, or objectivity by which the human research protocol is managed. The IO should also consult the Associate Vice President of Regulatory Affairs (AVPRA).

At a minimum, conflicted individual(s) will be excluded from the decision-making process and oversight of the research and will not be engaged to direct or take administrative actions. The evaluation criteria do not vary by funding agency or regulatory oversight. Evaluation considerations will include whether disclosure in the consent form is adequate to protect human subjects or if additional safeguards are needed. If the IRB determines that an organizational conflict of interest could affect the rights and welfare of participants, the integrity of data collected, or objectivity by which the human research protocol is managed, then the conflict of interest must be eliminated or a management plan implemented so that the rights and welfare of participants and integrity of the research project are not affected by the interest.

The IO will communicate with the Provost to assure that conflicted institutional leaders are relieved of administrative oversight of related human research projects when necessary. The key to avoiding these situations is awareness of what constitutes such conflicts, disclosure of potential situations before activity is undertaken, and a review of the situation. A determination may be made by the IO to, in certain cases, permit an activity, which may otherwise be considered a conflict, if it is (1) purely personal to the individual or beneficial to the university and (2) performed in full compliance with all legal,
regulatory and other requirements. Issues of actual or possible conflict, once disclosed to the IO, will typically be resolved by the IO and the General Counsel.

Details of organizational financial conflicts will be reported in the IRB minutes, including details of deliberations related to the conflicting interest.

**HRPP Staff COI**
If an HRPP staff member has been assigned to a project with which he/she has a potential conflict of interest, the HRPP staff member will notify the HRPP manager. The HRPP staff member shall be recused (excluded) from reviewing the project.

Information about conflict of interest is included in the pre-review forms completed by IRB staff when reviewing projects.

**Consultant COI**
Non-IRB members solicited for his or her additional expertise pursuant to Section 5-4, “Additional Expertise,” HRPP Manual must not have a conflict of interest when reviewing a protocol. If the individual or a member of his or her immediate family has a conflict of interest, he/she will be excluded from consideration as a consultant on the project. See Section 5-4, “Additional Expertise,” HRP Manual for procedures.

**IRB Member COI**
If an IRB member (including the IRB chair) has been assigned to review a project with which he/she has a potential conflict of interest, the IRB member should alert the IRB staff. The IRB staff will assign the project to another IRB member.

At convened IRB meetings, IRB members with a conflict of interest are:
- Excluded from discussion except to provide information requested by the IRB
- Excluded from voting
- Must leave the meeting room for discussion and voting (except to provide information requested by IRB)
- Not counted towards quorum.

The IRB staff will document in the IRB minutes that the IRB member left the room during the discussion and voting on the proposal, with an indication that a conflicting interest was the reason for the absence.

Several mechanisms are used to remind IRB members about conflict of interest. These include reminders on review checklists for initial, renewal, and revision applications, a statement in the email alerts sent to IRB members for applications assigned for review, and reminder at the convened IRB meeting to disclose conflicts of interests.

**IRB Review of Projects with Individual Conflicts of Interest**
In situations where the IRB deems that the conflict of interest management plan approved by the VPRGS under the Faculty Conflict of Interest Policy is not sufficient to protect the rights and welfare of human subjects, the IRB may refuse to approve the participation of
human subjects in that project. The IRB Chair will communicate and consult with the VPRGS if the IRB has concerns regarding any plan for the management of a conflict of interest relating to a research project involving human subjects.