



Policy Title	Conflicts of Interest
Last Updated	10-19-2021
Responsible Office	IRB Office
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## 1. Policy Purpose Statement

The keys to managing conflicts are disclosure and transparency. This policy lays the foundation for the review of reported conflicts. The review must consider the associated risk to human subjects and the integrity of research findings. This includes reported conflict of interests for all projects (sponsored and non-sponsored projects) regardless of the funding source for all Institutional Review Board (IRB) members, IRB Office staff, investigators, research staff, and organizational conflict of interest.

## 2. 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 their responsibilities. The individual does not have to do anything improper to have a conflict of interest; it could 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 their 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** This 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:

- 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 Office staff member holds a significant financial interest or by one of its competitors.
- Another KSU 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 member or IRB Office staff member.

**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.

**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:

- KSU salary, remuneration by KSU, or other payments at KSU's behest (including from an KSU-approved practice plan);
- Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels paid by:
  - Federal, state, or local U.S. government agencies;
  - U.S. institutions of higher education;
  - U.S. academic teaching hospitals and medical centers;
  - 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 KSU'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.

### 3. Policy

**3.1.**All KSU faculty and staff are required to follow the Conflict of Interest policy for the institution and the University System of Georgia which are found at <https://coi.kennesaw.edu/index.php> and <https://www.usg.edu/policymanual/section8/C224/#n82182>. KSU Faculty and staff who are IRB members must additionally adhere to the terms of this policy. Requirements for IRB Members who are not affiliated with KSU are limited to the terms of this policy.

**3.2.**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:

- 3.2.1.** Excluded from discussion except to provide information requested by the IRB
- 3.2.2.** Excluded from voting
- 3.2.3.** Must leave the meeting room for discussion and voting (except to provide information requested by IRB)

- 3.2.4.** Not counted towards quorum.
- 3.3.** 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. Investigators, research staff, and consultants (including agents of KSU, or others not employed by KSU) 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:
- 3.3.1.** 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
- 3.3.2.** 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.
- 3.4.** Investigators must include 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.
- 3.5.** If a potential conflicting interest arises after IRB approval for any member of the study team, the PI must notify the IRB within 5 days of knowledge of the conflict ,by submitting a modification 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 KSU COI Policy should be followed by KSU faculty and academic staff.
- 3.6.** The IRB will consider whether additional measures should be added to the management plan and may work with the Director for Research Compliance in formulating a plan to protect the rights and welfare of the human research participants which may include informing previously enrolled participants.
- 3.7.** If the IRB determines the management plan to be inadequate to protect the rights and welfare of the human research participants, the IRB may disapprove the research. In this event, the IRB will communicate these findings to the Director for Research Compliance.