

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

- x 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 IRBmember 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:

- x Payments for services such as consulting fees, salary, honoraria, or commissions.
- x Equity interests like stock and stock options.
- x Other ownership interests, like being a partner in a partnership or operating an unincorporated business.
- x Beneficial interests, i.e., being the beneficiary of a trust or estate or a trustee of a trust or

The following financial interests are excluded from consideration and do not need to be reported:

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

- 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 the subject.