

SOP- Conflict of Interest
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Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Conflict of Interest

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Associate Vice Chancellor for Research

A handwritten signature in cursive script that reads "Michele Kennett".

1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for conflict of interest (COI) related to research.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

University of Missouri's Conflict of Interest Committee

The Conflict of Interest (COI) Committee at the University of Missouri has been charged by the Chancellor with the responsibility for management of all conflicts of interest on the University of Missouri campus. The Committee works to assist faculty and staff to appropriately structure their various interests to reduce and eliminate potential risks. The University of Missouri's policy requires disclosure of outside interests annually and/or whenever an outside interest arises or changes. Conflicts are disclosed within the COI

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module in eCompliance. Management plans, if necessary, are also documented within the COI module.

All employees of the University of Missouri are subject to the requirements within the Collected Rules and Regulations. It is the obligation of all University employees, regardless of position or length of employment, to self-disclose any outside employment or business activities and interests that could interfere with the employee's regular duties or represent a conflict of interest (University of Missouri Collected Rules and Regulations, [Section 330.015.D](#)). The COI office is responsible to educate researchers and research staff about disclosures and responsibilities related to financial conflict of interest. Education includes utilization of COI modules within the CITI training modules for initial and refresher training, annual communication with employees through email, and through departmental interactions such as faculty meetings and meetings with department chairs and deans.

Per 420.030 Conflict with the Interests of Federal Grant Agencies, each investigator involved in any PHS- or NSF- funded grant or contract shall complete training prior to engaging in research related to such grant or contract; shall complete training at least every four years; and shall complete training immediately if (a) there is a change in this policy that affects investigator requirements, (b) the investigator is new to the University, or (c) the University finds the investigator noncompliant with this policy or management plan created pursuant to this policy. The policy may be found here:

https://www.umsystem.edu/ums/rules/collected_rules/research/ch420/420.030_conflict_with_the_interests_of_federal_grant_agencies

Additional COI committee review information can be found here:

https://research.missouri.edu/compliance/conflict_of_interest/index.php

MU COI Committee Procedures can be found here:

https://research.missouri.edu/compliance/conflict_of_interest/files/MU_COI_Procedures_2019.pdf

The MU COI committee works with the IRB in ensuring financial conflicts of interest are managed and minimized or eliminated, when appropriate.

Conflicts Related to Human Subject Research Activities and IRB Review

University of Missouri employees must have a financial interest disclosure form on file with the COI office prior to the approval of an IRB application, even if there are no conflicts to disclose and/or manage. The COI committee reviews the disclosed conflict(s) according to their policies and develops a management plan, if necessary. The MU HRPP/IRB Director serves on the advisory council to the COI committee and is in attendance at monthly COI committee meetings. In addition, the COI office utilizes the resolution of “IRB” for any specific conflicts if the conflict is or could be related to a particular human subject research project. This IRB resolution identification is shared on a

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monthly basis with the HRPP/IRB office and reviewed for any active studies to determine if any additional action is needed with respect to any research studies.

If a financial conflict of interest is identified within the COI disclosure form, the IRB office has access to review the disclosure form to ensure it matches what is disclosed within an IRB application or other IRB submission. In addition, the integration of the COI and IRB modules within eCompliance provides the ability to flag all personnel who are added to an IRB application that have any known conflicts of interest and HRPP/IRB staff have the ability to review not only recent COI disclosures by researchers, but previous years' disclosures as well. It would then be reviewed and managed as part of the review of the IRB application or other submission form. Research records related to conflicts of interest comply with the MU HRPP/IRB Record Retention policy.

Financial conflicts of interests in human subjects research may present real or perceived risks to the rights and well-being of subjects. To ensure the integrity of research and its compliance with applicable laws and regulations, and the institution's legitimate interest in the financial health and economic viability of the enterprise, institutions should ensure that the responsibility for human subjects research does not overlap or coincide with interests that may be directly affected by the outcome of the research. Institutions should ensure that the functions and administrative responsibilities related to human subjects' research are separate from those related to investment, management, and technology licensing and other business interests of the Institution. Conflicts of Interest may be either financial or non-financial, indirect or direct interests. Conflicts of interest are not always prohibited, but conflicts must be managed or eliminated so that they do not adversely affect participant protections or the credibility of the human research protections program.

A. Investigator/Research Team COI Disclosure and Management

Any investigator or other person responsible for the design, conduct, or reporting of research (including spouses and dependent children) that may have a conflict of interest with any proposed research will have that conflict evaluated and managed by the IRB.

Each investigator shall disclose all interests that would reasonably appear to directly and significantly affect the funded research or educational activities. The following financial interests of all individuals involved in the design, conduct, or reporting of the research and their spouses and dependent children must be disclosed:

- a. Ownership interest, stock options, or other financial interest related to the research of any amount.
- b. Compensation or in kind remuneration related to the research of any amount.
- c. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- d. Board or executive relationship related to the research, regardless of compensation.

This information must be disclosed:

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- a. at the time the IRB proposal is submitted;
- b. on an annual basis during the project annual renewal; and
- c. immediately as new conflicts arise.

If VA regulations apply, researchers must disclose conflicts of interest. This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that might affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.

IRB Management of Research Conflicts of Interests

The IRB reviews research for conflicts of interest and has the final authority for the management of the conflict under IRB review and determines whether the research can be approved.

The COI office provides access to monthly reports which highlight investigators with conflicts that are referred to the IRB as part of their management plan. These reports and management plans are reviewed regularly and are included as part of the MU HRPP/IRB monitoring program to ensure proper follow-up with the investigator/research team if the conflicts have not been properly disclosed to the IRB or managed by the IRB.

Examples of how research conflicts of interest might be managed by the IRB include the following:

1. Public disclosure of significant interests via the consent process and in publications and presentations;
2. Monitoring of all or a portion of the research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in all or a portion of the research; and/or
5. Divestiture of significant interests.

B. Board member and Consultant Conflict:

No IRB member, their spouse or dependent children, or consultant may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB member (their spouse and dependent children) or consultant is considered to have a conflicting interest when any of the following are true:

1. There is ownership interest, stock options, or other financial interest related to the research;
2. They receive compensation related to the research;
3. They have a proprietary interest related to the research;
4. There is an executive relationship related to the research;
5. Involvement in the design, conduct, or reporting of the research;

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6. When assisting in development of the study;
7. When there is a personal or professional conflict with the other members listed on the study;
8. The IRB member or consultant believes that will be unable to impartially review a research protocol; and
9. The IRB member has identified him or herself for any other reason as having a conflicting interest.

IRB staff will remind members of COI policies at each meeting. Educational materials are available for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects' research.

Each board member has the responsibility of making the IRB staff aware of a conflict of interest. Prior to any review assignments, the IRB staff will check for any potential conflict of interest. The COI policy applies to each board member for all types of reviews.

IRB staff will ask consultants about conflicts prior to review assignment.

See the Board Meeting Procedures and Minutes SOP regarding board member and consultant conflicts during an IRB meeting.

Rules, Regulations, Policies, and Procedures:

The University of Missouri-Columbia has several policies governing COI:

- Collected Rules and Regulations on COI:
https://www.umsystem.edu/ums/rules/collected_rules/personnel/ch330/330.015_policy_on_conflict_of_interest
- Collected Rules and Regulations on Institutional Conflicts of Interest:
https://www.umsystem.edu/ums/rules/collected_rules/research/ch410/410.020_institutional_conflicts_of_interest_in_human_subjects_research
- Collected Rules and Regulations on Conflict with the Interests of Federal Grant Agencies:
https://www.umsystem.edu/ums/rules/collected_rules/research/ch420/420.030_conflict_with_the_interests_of_federal_grant_agencies
- MU Conflict of Interest Committee Policies and Procedures:
https://docs.research.missouri.edu/human_subjects/SOP_Conflict_of_Interest.pdf

References:

Policy Revision Dates Prior to January 21, 2019:

June 1, 2004; December 12, 2005; December 1, 2006; June 10, 2010; July 1, 2011;
March 1, 2015; July 1, 2015; January 29, 2016; June 8, 2017