Conflict of Interest

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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.

2.0 Scope
The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.

3.0 Policy/Procedure
General Information
An institution may face a conflict among its multiple duties to protect human 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 responsibility for those institutional financial 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.

Conflicts of Interest may include either financial (direct) or non-financial (indirect) interests. Certain conflicts of interest are not always prohibited because not all interests cause conflicts that impact research. Conflicts must be managed so that they do not adversely affect participant protections or the credibility of the human research protections program.

When investigators have specific financial relationships or other non-financial interests in research the disclosure must be forwarded to the Conflict of Interest committee for review [http://www.research.missouri.edu/complia/coi.htm](http://www.research.missouri.edu/complia/coi.htm). The Conflict of Interest committee will evaluate the conflict and provide a recommendation to the IRB. The IRB will review and act on the recommendation.

**Direct Financial Relationships**
Institutions and individuals involved in human subjects’ research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property. When such direct financial interests are disclosed, the disclosure is forwarded to the Conflict of Interest committee for review.

**Indirect Non-financial Interests**
Private interests in outside organizations can result in COI. Examples of private interests include unpaid leadership positions, membership on the board of directors, companies, clubs, societies and organizations such as trade unions and voluntary organizations, which members of the public might reasonably think could influence the decision-making process. When such indirect, non-financial interests are disclosed, the disclosure is forwarded to the Conflict of Interest committee for review.

**Financial Interest Related to the Research**
Financial Interest related to the sponsor, the product or service being tested, or a company with a financial interest in the sponsor, or the product or service being tested.

**Board member and Consultant conflict:**
No IRB member 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 or consultant is considered to have a conflicting interest when any of the following are true:

An IRB member or consultant is considered to have a conflicting interest when any of the following are true:

- When the member, consultant, or a member or their spouse or dependent children have an ownership interest, stock options, or other financial interest related to the research.
- When the member, consultant, or a member or their spouse or dependent children receive compensation related to the research.
- When the member, consultant, or a member or their spouse or dependent children have a proprietary interest related to the research.
• When the member, consultant, or a member or their spouse or dependent children have a board or executive relationship related to the research.
• When the member, consultant, or a member or their spouse or dependent children are involved in the design, conduct, or reporting of the research.
• The IRB member or consultant believes that will be unable to impartially review a research protocol.
• When the member is listed on the study or has assisted in developing the study
• When the member has a has a personal or professional conflict with the other members listed on the study
• Or if the IRB member has identified him or her self for any other reason as having a conflicting interest.

IRB staff will remind members of conflict of interest 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 conflict of interest policy applies to each board member for all types of reviews, including expedited reviews.

IRB staff will ask the consultant about conflicts prior to review assignment.

Any member (including chairs) that has a conflict of interest with any research reviewed by the Board must excuse him/herself from the meeting prior to any discussion of the project and during the vote. The member may be invited into the meeting to answer questions; however the member will be excused during the Board deliberations. If a chair is excused from the meeting due to a possible COI, a board member will take over the deliberations for that particular project in the absence of the chair.

If a member is excused from the meeting due to a conflict of interest, a valid quorum must be present or the meeting must be terminated from further action until a valid quorum is obtained.

Investigator or other study staff conflicts:

Any investigator or other person responsible for the design, conduct, or reporting of research (to include spouses and dependent children) that may have a conflict of interest with any proposed research will be forwarded to the Conflict of Interest Committee. Each investigator shall disclose to the COI committee all interests:

1. That would reasonably appear to be directly and significantly affected by the funded research or educational activities; or

2. 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:
   • Ownership interest, stock options, or other financial interest related to the research of any amount.
   • Compensation related to the research of any amount.
• Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

• Board or executive relationship related to the research, regardless of compensation.

This information must be disclosed:

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.

The Conflict of Interest Committee, under the auspices of the Deputy Chancellor, independently determines whether the COI can be effectively managed, reduced or eliminated, working with the investigator and the IRB. The COI committee notifies the IRB, in writing, of the final determination and management plan in the case. The IRB may accept the plan, reject the plan, or require additional protections. Disclosure to participants may not be used alone to manage a financial interest that may affect participants protections. The IRB has final authority to decide whether the conflicting interest and its management allows the research to be approved.

If the COI committee determination was not available at the time of initial review by the IRB the study will be deferred and will return to the IRB for review of the COI committee determination and management plan.

Examples of how conflicts of interest might be addressed include the following:

• Public disclosure of significant interests via the consent process

• Monitoring of research by independent reviewers

• Modification of the research plan

• Disqualification from participation in all or a portion of the research

• Divestiture of significant interests

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

• Business Policy and Procedures on COI:

• Collected Rules and Regulations on COI:

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