

Conflict of Interest
Policy Number 2876.15



Campus Institutional Review Board
University of Missouri-Columbia


Conflict of Interest

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Approval Authority:


Signed
IRB Chair

Date December 12, 2007

Institutional Approval:


Signed
Associate Vice-Chancellor for Research

Date December 12, 2007

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1.0 Policy

The Campus Institutional Review Board (Campus IRB) assures that its operations will include a mechanism that will be in place to identify, disclose, manage, and if possible, resolve conflicts of interests to promote ethically sound research involving human subject participants. All Campus IRB activities shall be conducted in the absence of institutional interference, in compliance with the policy outlining the “Authority of the Campus IRB.” All financial conflicts of interest will be reported to the Conflict of Interest committee by completing a “Disclosure form.” The Campus IRB reserves the right to maintain the final authority to decide whether the conflicting interest and its management will permit the research proposal to be approved.

2.0 Scope

The spirit of the Campus IRB is to ensure that the interests and dignity of every research participant is diligently protected through a system that manages any Conflict of Interest potentially impacting the subject.

3.0 Purpose

The Campus IRB is charged with overseeing the ethical conduct of research involving human subjects. It is critical that the IRB operate in a system free from inappropriate influence to assure that researchers don’t permit a set of conditions to exist in which the investigator’s judgment concerning a primary interest (such as the subject’s welfare, or the integrity of the research) may be biased, compromised or considered a secondary interest lacking priority over the IRB process.

4.0 Standard Operating Procedures

The Campus IRB and MU Conflict of Interest Committee defines a “*conflict of Interest*” as an instance when there is a convergence between an individual’s personal financial, relational, or other interests and his/her professional obligations to the University of Missouri such that an independent observer might reasonably determine that the individual’s professional actions or decisions are adversely affected, distorted or otherwise compromised by the individual’s personal interests.

All members are screened prior to their appointment on the board. All members are provided a copy of the Campus IRB policies, and notified of the Conflict of Interest disclosure requirements. No member or consultant may participate in the review of any proposal in which there is a conflicting interest, except to provide information requested by the Campus IRB. Members are expected to self-identify conflicting interests to the Chair and Compliance Officer so the proposal may be assigned to another member. Members are expected to absent themselves from the convened meeting when research in which they have a conflicting interest is reviewed, which will be reflected in the Minutes. The Chair will allow for discussion and deliberation once the conflicted member has been recused. The absent member may not be counted toward quorum during the discussion and vote on the protocol for which there is a conflicting interest. The minutes will note the activity in accordance with the “Minutes” and “Board Meeting Procedures” policy.

Consultants are either solicited to provide an expert review of an entire protocol or a specific issue associated with a protocol. Consults must comply with the “Conflicts of Interest” policy described herein. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

Identification of a conflict if interest is an important step in the Management process, encouraging a variety of “disclosure methods” in an effort to protect human subjects and maintain the integrity of the IRB processes.

I. INVESTIGATOR CONFLICTS OF INTEREST

IDENTIFYING CONFLICTS OF INTEREST

The presence of Conflicts of Interest on any aspect of the IRB review processes could potentially undermine the credibility of the Campus IRB, and should be addressed when possible. The Campus IRB is not immune from the possibility that it is as vulnerable to the presence of a Conflict of Interest as any other organized committee.

The Campus IRB recognizes that there are 4 Conflict of Interest areas that members must self-report to the Chair and CIRB Compliance Officer:

1. Personal – When an individual possesses a personal opinion or idea about another individual, which may impact a decision made about that individual.
2. Professional - When an individual’s professional opinion or idea about another individual, may impact a decision made about that individual.
3. Financial – When an individual possesses a financial interest in a research proposal.
4. Institutional – When the institution possesses an interest which may impact a decision made about the research project.

A. PERSONAL or Professional: INDIVIDUAL CONFLICTS OF INTEREST

When reviewing any proposal, the Campus IRB member must assess for the presence of any conflicts of interests with other research team members or persons responsible for the design, conduct, or reporting of research; spouses; immediate family members or dependent children.

Examples:

1. Personal Interests: Self-serving interests.
2. Conflicting Roles: The presence of community responsibilities that conflicts with the central mission of the University of Missouri-Columbia Human Subject Research protection program.

B. INSTITUTIONAL CONFLICTS OF INTEREST

When reviewing a proposal, the Campus IRB member must assess for the presence of any conflicts of interests of other research team members or persons responsible for the design, conduct, or reporting of research; spouses; immediate family members or dependent children.

Examples:

1. Protecting the Institution: Department Heads have a natural expectation to perform on behalf of the institution’s research mission. The IRB member’s role as a faculty, staff, or agent of the institution should not be incompatible with the role as an IRB member. Both positions may coexist so long as the member makes IRB decisions free of bias tendencies.
2. Enhancing the Institution’s Reputation: The institution’s reputation is not incompatible with the researcher or member’s role, and should never be an excuse for relaxing IRB standards.
3. Promoting Research: This conflict is more perplexing to members, in that a Research Institution’s mission includes the promotion of the research objective. This conflict may continue to be the institution’s mission so long as it doesn’t distract from the charge of the IRB.
4. Value of Membership: A researcher and member must value their role to avoid jeopardizing the mission of the IRB review process.
5. Liability: It is important that an IRB consider the legal ramifications presented in a proposal, as “part” (not “all”) of the process.
6. Institutional or Community Values: IRB activities are conducted in a manner where external values will not hinder the IRB decision-making process.

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7. Pressure to speed up reviews: While efficiency of IRB reviews is desirable by researchers, the researcher should not expect to influence the review process to the point that standards are relaxed.
8. Institutional Holdings or Interests: The institution is not prohibited from entering agreements and developing new innovations so long as the conflict is managed in such a way that it doesn't interfere with the charge of the IRB. Securing an unaffiliated independent IRB to conduct the review is also an option.
9. Review Fees: There is nothing inherently wrong with charging review fees, so long as there is a written agreement to facilitate management of the conflict.

C. FINANCIAL CONFLICTS OF INTEREST

The Campus IRB requires researchers to disclose the presence of any conflicts of interests with other research team members or persons responsible for the design, conduct, or reporting of research; spouses; immediate family members or dependent children. The conflict may also occur with the sponsor of the study, the supporting organization, or company that owns or license the technology being researched.

The University of Missouri-Columbia has an independent Conflict of Interest Committee whose membership is comprised of a diverse representation of the research community. The committee has a higher standard of review than provided by the regulations and requires ALL financial conflicts of interest to be reviewed by the panel.

The Conflict of Interest Committee, under the auspices of the Deputy Chancellor, independently determines whether the COI can be effectively managed, reduced or eliminated, by coordinating efforts between the investigator and the IRB. The COI committee provides the IRB with written notification of the final decision of the committee and management plan for the activities.

The Campus IRB has the final authority to accept the plan, reject the plan, or require additional procedures be implemented to further protect human subject participants. Investigators must provide the IRB with information related to the COI plan, and how they propose to protect subjects.

The IRB has final authority to decide whether the conflicting interest and its management plan is permissible, and whether the research activities can be approved. If the COI committee determination was not available at the time of initial review by the IRB the study will not be approved, and will be deferred for action at the time of the COI committee's final determination and approval of the 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

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An investigator must disclose financial relationships involving the following:

1. Any ownership interest, stock options, or other financial interest related to the research unless it met four tests:
 - Less than \$10,000 when aggregated for immediate family member.
 - Publicly traded on a stock exchange.
 - Value would not be affected by the outcome of the research.
 - Less than 5% interest in any one single entity.
2. Any compensation related to the research unless it met two tests:
 - Less than \$10,000 in the past year when aggregated for immediate family.
 - Value would not be affected by the outcome of the research.
3. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
4. Board or executive relationship related to the research, regardless of compensation.

II. RECOMMENDATIONS TO THE INVESTIGATOR

A. REQUIRED DISCLOSURES IN THE IRB PROCESS

The Investigator conducting research under the jurisdiction of the Campus IRB must disclose the conflict of interest to the appropriate agencies, committees, or boards when applicable. The researcher must assure the following disclosures are made, if applicable:

1. Disclosure to Governmental Agencies
2. Disclosure to the MU Conflict of Interest Committee
3. Disclosure to the Campus IRB

B. PROCESS FOR DISCLOSURES

1. Disclosure to Governmental Agencies

The investigator must inform the appropriate regulatory authority of the presence of a conflict of interest for governmentally funded projects. The investigator should make sure to understand all of the terms of the agreement and any required disclosures associated with the research activities funded by a government agency and comply with said agreement. The investigator should notify the Campus IRB of all disclosures to Governmental Agencies to assure compliance with regulations and policies governing the IRB process.

2. Disclosure to the Conflict of Interest Committee (“COIC”) (Mandatory)

When investigators have specific financial relationships or other non-financial interests in research and appropriately disclose those interests directly to the COIC for review, the committee will evaluate the disclosure and make a determination as to whether a conflict exists. Should that disclosure involve a research project involving human subjects, the COIC will provide a copy of the final resolution to the appropriate IRB office for consideration in the board deliberations regarding the protocol. The investigator should contact the Conflict of Interest Committee if they have questions as to whether disclosure is required. (Office of Research (573) 882-9500). See also Office of Research Conflict of Interest Policy: <http://research.missouri.edu/complia/coi.htm>

If an investigator has questions, they should contact the office of the Vice-Chancellor for Research/Director of Research Compliance, 205 Jesse Hall - University of Missouri-Columbia, MO 65211: (573) 882-9500.

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3. Disclosure to the Campus IRB (Mandatory)

When investigators have specific financial relationships or other non-financial interests in research and disclose those interests directly to the IRB, the IRB office will follow the procedure outlined below to direct the investigator to the COIC for appropriate review of such disclosure.

The IRB office will contact the investigator and instruct him/her to complete the appropriate disclosure form. Should the investigator submit such form directly to the IRB office, the IRB may forward the form to the COIC administrator on behalf of the investigator or return it to the investigator with instructions to submit the disclosure form to the COIC for review.

Upon receipt of a complete disclosure form, the COIC will evaluate the disclosure and make a determination as to whether a conflict exists. The COIC will provide a copy of the final resolution to the appropriate IRB office for consideration in the board deliberations regarding the protocol.

IRB and Investigator involvement in COIC Review

In the review of a disclosure concerning human subjects research, the COIC will independently determine whether the COI can be effectively managed, reduced or eliminated. However, the COIC will coordinate with the investigator and the IRB to gain any necessary information regarding the protocol and the conflict to ensure that the final resolution is appropriate and made with full knowledge of material facts.

Ex Officio Membership

The IRB office administrators will be assigned to the COIC as ex officio members to enhance communication efforts between the COIC and the IRB offices.

C. **CAMPUS IRB PROCESS TO MANAGE DISCLOSURE**

When investigators have specific financial relationships or other non-financial interests in research and disclose those interests directly to the Campus IRB, the following procedure will be implemented in compliance with the MU Conflict of Interest Committee for review of the disclosure.

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| Step 1 | The investigator completes the eIRB application and identifies the Conflict of Interest |
| Step 2 | The reviewer must identify what category of conflict is being disclosed. |
| Step 3 | The IRB office will contact the investigator and give directions to complete the appropriate disclosure form. Should the investigator submit such form directly to the IRB office, the office may forward the form on the to COIC administrator on behalf of the investigator or return it to the investigator with instructions to submit the disclosure form to the COIC for review. |
| Step 4 | Upon receipt of a complete disclosure form, the COIC will evaluate the disclosure and make a determination as to whether a conflict exists. The COIC will work with the investigator and the involved IRB as appropriate to gain necessary information regarding the protocol and the conflict to ensure that the final resolution is appropriate and made with full knowledge of material facts. The COIC will provide a written copy of the final resolution to the appropriate IRB office for consideration in the board deliberations regarding the protocol. |
| Step 5 | The IRB process will not move forward until a decision has been made by the Conflict of Interest committee. |

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Step 6 The IRB reserves the right to review the decision and make a determination regarding the approval status of the proposal. The presence of a Financial Conflict of Interest will subject a project to a final determination for approval by a convened IRB. The convened IRB has the final authority to decide whether a conflicting interest and its management processes proposed can be approved. The Campus IRB will take ACTION in compliance with the “Campus IRB Review Process” and “Board Meeting Procedures” policies.

D. WHEN DISCLOSURES ARE REQUIRED DURING THE CONSENT PROCESS:

The Campus IRB will require disclosure of the financial interest to participants in the consent form if a financial conflict of interest, as defined by this policy or the MU Conflict of Interest Committee, is identified.

The Campus IRB requires the disclosure of the following financial interests of investigators and other persons responsible for the design, conduct, or reporting of research, and their spouses and dependent children in the Informed Consent Processes.

E. FINAL CAMPUS IRB DETERMINATION

1. The presence of a Financial Conflict of Interest will subject a project to a final determination for approval by a convened IRB. The convened IRB has the final authority to decide whether a conflicting interest and its management processes proposed can be approved.

2. When reviewing a proposal, the process will be conducted in compliance with the “CIRB Review Process”; “Board Meeting Procedures”; and “Minutes” policies. The Primary Reviewer must assess for the presence of any conflicts of interests of other research team members or persons responsible for the design, conduct, or reporting of research; spouses; or dependent children and present the information to the convened board. The reviewer IS ALSO REQUIRED to evaluate the financial conflict of interest to determine:

- a. What is the effect of the financial interests on participant protections?
- b. How will the conflict be managed to avoid adversely affecting participant protections or the credibility of the human subject research protection program?

The convened Campus IRB has the authority to render a decision regarding the approval status of the proposed research.

III. CONFLICT OF INTEREST WITH A CAMPUS IRB MEMBER

A. PROCESSES FOR IDENTIFYING A CONFLICT OF INTEREST

A conflict of interest may also potentially be present with a Campus IRB member. The Campus IRB will address conflicts of interest among the membership with the same level of responsibility as it does with investigators. Any member having a conflict of interest shall report it to the Campus IRB Chair or Compliance Officer immediately.

The Campus IRB recognizes that a member may have 4 Conflicts of Interest:

1. Personal – When an individual possesses a personal opinion or idea about another individual, which may impact a decision made about that individual.
2. Professional - When an individual’s professional opinion or idea about another individual, may impact a decision made about that individual.
3. Financial – When an individual possesses a financial interest in a research proposal.
4. Institutional – When the institution possesses an interest which may impact a decision made about the research project.

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Examples:

1. Research conducted by IRB members: The member shall inform the Campus IRB immediately. The member will be excused from any aspect of the review process, except to provide information to board if requested, deliberation and voting activities. The member will also be prohibited from accessing any relevant “internal” IRB records related to the research. This includes any other proposals associated with the member’s research.
2. IRB members with financial interests: The member SHALL inform the Campus IRB and be referred to the “Conflict of Interest Committee” for disposition. The Campus IRB may restrict activities or modify the proposal status *pending a disposition* from the Conflict of Interest Committee. The Campus IRB has ultimate authority regarding the approval status of the research proposal.
3. IRB member loyalty to colleagues: The member shall avoid promoting or endorsing a proposal out of departmental or unit allegiance, and notify the Campus IRB of the conflict PRIOR to participating in review activities.
4. Member’s area of expertise: The member shall avoid being either more lenient or strict in the review process because of their position within a department, unit or field of expertise. The member should make every effort to avoid taking advantage of access to investigator’s proprietary information that may serve to enhance their respective area of expertise. The member shall notify the Campus IRB and refrain from participating in any associated review processes.

B. MANAGING A CONFLICT OF INTEREST WITH A CAMPUS IRB MEMBER

The Campus IRB member is expected to report the presence of a conflict of interest to the IRB Chair/CIRB Compliance Officer while performing all functions on behalf of the committee. Members are expected to self-identify conflicting interests so the proposal may be assigned to another member. No member may participate in the review of any proposal in which there is a conflicting interest, except to provide information requested by the Campus IRB. Members are expected to absence themselves from the convened meeting when research in which they have a conflicting interest is reviewed. The Chair will allow for discussion and deliberation once the conflicted member has been recused. The absent member may not be counted toward quorum during the discussion and vote on the protocol for which there is a conflicting interest. The minutes will note the activity in accordance with the “Minutes” and “Board Meeting Procedures” policy.

REPORTING REQUIREMENTS:

1. The member shall immediately notify the Board Chair and Compliance Officer of the nature of the conflict. The member should make every attempt to make said notification before the convened meeting, or as soon as the matter is identified.
2. If the conflict is not self-identified but brought to the attention of the Board Chair, Compliance Officer, or by any other Campus IRB member or staff – the member will be notified immediately.
3. The member shall not access any IRB records, correspondence, or communications related to the conflicting matter at issue without the express consent of the Campus IRB.
4. The Campus IRB shall be informed of the conflict of interest and obtain any requested information needed from the member to make a decision;
5. The Campus IRB will review the matter in a manner to properly manage the conflict or at an appropriate level of review in accordance with all Campus IRB policies.
6. The Campus IRB Member will be informed of the nature of the conflict and decision by the Campus IRB Compliance Officer or Board Chair. Notice will be sent to the appropriate individuals, agencies, organizations, units, departments, etc. as the IRB deems appropriate.

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C. TYPES OF REVIEW

Conflicts of interest will be reviewed at the appropriate level of review (Exempt, Expedited or Full Board) in accordance with Campus IRB policies and procedures. The reviewer must comply with the “Campus IRB Review Process” and “Level of Risk” policies and complete the “Board Member Review Checklist” to complete the process.

Conflict of Interest Matters Reviewed at a Convened Meeting:

When a conflict of interest meets the criteria for Full Board review, it will be docketed on the agenda in accordance with the “Agenda”, “Board Meeting Procedures”, and “Campus IRB Review Process” policies. The board shall have the discretionary authority to determine whether the member needs to be present during meeting discussions to provide information to the Campus IRB. The convened IRB has the final authority to decide whether a conflicting interest and its management processes proposed can be approved.

DOCUMENTATION

- a. The Minutes shall reflect:
 - i. The identity of the member and the specific nature of the conflict.
 - ii. The information or documents submitted to the Board by the member;
 - iii. The precise time the member is excused from the meeting and returns;
 - iv. That a valid quorum is maintained in the absence of the board member. If a valid quorum cannot be maintained, the meeting shall be terminated from further action until quorum can be restored;
 - v. The precise time deliberations were conducted and concluded.
 - vi. The final vote and action.

<p><i>Revised December 2006</i> <i>Revised June 2007</i> <i>Revised December 2007</i></p>
