

SOP: 104B
CONFLICT OF INTEREST – IRB MEMBERS

1. Policy

All Institutional Review Board (IRB) members and consultants to the IRB shall disclose in writing to the IRB all conflicts of interest for themselves and their spouses/domestic partners and dependent children. For purposes of this policy, a conflict of interest arises when an IRB member or consultant holds an economic interest that could affect or appear to affect the design, conduct, oversight, or reporting of the research. Economic interests that require disclosure include but are not limited to:

- a. Ownership interest, stock options, or other economic interest related to the research unless it is all of the following:
 - i. Less than \$10,000 when aggregated for the investigator, investigator's spouse, domestic partner, and dependent children;
 - ii. Publicly traded on a stock exchange;
 - iii. An amount that will not be affected by the outcome of the research;
and
 - iv. Less than 5% interest in any one single entity.
- b. Compensation related to the research unless it is both of the following:
 - i. Less than \$10,000 in the past year when aggregated for the immediate family; and
 - ii. An amount that will not be affected by the outcome of the research.
- c. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- d. Board, scientific officer, or executive relationship related to the research, regardless of compensation for that position.

An IRB member or consultant with a conflict of interest in a research project involving human participants may not participate in the IRB review of that research. The IRB shall not approve a research protocol where a conflict of interest is not eliminated, and it has the final authority to determine whether a conflict of interest has been eliminated appropriately.¹

IRB members and consultants shall cooperate fully with the IRB and any other individuals or groups involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed.

This policy is not intended to prohibit IRB members' relationships with companies that have no influence on the design, conduct, or reporting of a study and that occur prior to

¹ If non-research related conflicts are identified by the IRB, IRB approval of a means to manage a conflict of interest is not final University approval for the research to be conducted. The appropriate vice-president or his/her designee under the Policy Regarding Conflict of Interest - Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus has final authority to allow or disallow research. However, no research involving human participants may be conducted by OU investigators if the IRB has not approved it.

the initiation of a sponsored study or after publication of its results. However, that notwithstanding, compensation in the form of an economic interest that may be affected by the outcome of the study shall be avoided. (Examples of conflicts of interest due to compensation that require disclosure pursuant to this Policy include, but are not limited to, consulting agreements, speaking or other fees, honoraria, gifts, licensing revenues, equity interests, loans or notes, including stock options, regardless of value, expectations of receiving equity interests, and/or other fees or compensation received from sponsors.)

2. Scope

This policy and its procedures apply to all University of Oklahoma IRB members and consultants to the IRBs.

3. Responsibility

A. IRB Member/Consultant Responsibilities

1. IRB members and consultants shall disclose to the IRB all conflicts of the IRB member/consultant, their spouse/domestic partner, and their dependent children with regard to a research project involving human participants. Such disclosure shall be sufficiently detailed and timely to allow the IRB Administration to transfer the project to another IRB or allow time for an alternate member or consultant to attend the IRB meeting. The IRB member/consultant shall evaluate whether a conflict of interest exists, and he/she shall disclose any identified conflicts to the IRB at the next IRB meeting.
2. If an IRB member/consultant discovers that he/she has a conflict of interest during the conduct of a study over which the IRB provides oversight, the IRB member/consultant shall report the conflict to the IRB at the next IRB meeting.
3. IRB members/consultants shall cooperate with the IRB and other officials in their review of the conflicts of interest issues and shall comply with all requirements of the IRB and/or the appropriate vice president under the Policy Regarding Conflict of Interest - Health Sciences Center or the Financial Conflicts of Interest Policy - Norman Campus to eliminate the conflict before the IRB will approve the project or continue the project.

B. IRB Responsibilities

1. After the IRB member/consultant discloses to the IRB a potential conflict of interest, the IRB shall require the member/consultant to recuse him/herself from review of the study.
2. Upon the member's/consultant's recusal, the IRB shall review the study pursuant to HRPP policy (SOP 403, Initial Review – Criteria for IRB Approval.)

4. Applicable Regulations and Guidelines

None.

5. References to Other Applicable SOPs

303B, IRB Meeting Administration
403, Initial Review – Criteria for IRB Approval.

6. Attachments

None.

7. Process Overview

7.1 Convened Meeting

- 7.1.1 The IRB Administrator checks the agenda prior to the meeting to identify IRB members who may have a conflict of interest. If a conflict of interest is identified, the study is assigned to a member who does not have a conflict of interest.
- 7.1.2 If the conflict has the potential to affect quorum, the IRB Administrator will ask an alternate to join the meeting to meet quorum, if possible.
- 7.1.3 The IRB Administrator and HRPP Director or designee reminds the IRB member to recuse him/herself before the review. A member who has a conflict of interest must recuse him/herself from the convened meeting. The recused member can answer questions from the Board, but cannot be present for Board deliberations and voting. If the conflict affects quorum, see SOP 303B, IRB Meeting Administration.
- 7.1.4 The recusal of the Board member is recorded in the IRB meeting minutes.

7.2 Expedited Review

- 7.2.1 IRB members who are conducting expedited review must disclose conflicts of interest and must not review those items.
- 7.2.2 The IRB Administrator identifies IRB members who are conducting expedited review who have a conflict of interest with a study. Items identified to have a conflict of interest by the IRB Administrator are presented to an IRB Chair or designee who does not have a conflict with the study.

APPROVED BY: _____

DATE: 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012