

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 may be identified as either financial in nature (such as when an IRB member or consultant holds an economic interest in the research) or non-financial in nature (such as when an IRB member or consultant participates in the research or will be included as a co-author on a publication from the research), either of which could affect or appear to affect the design, conduct, oversight, or reporting of the research project.

Financial 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 individual, individual'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.
- e. Interests that exceed \$1,000 in dividends or similar interests derived during the preceding calendar year.
- f. Annual income for professional or consulting activity from a company that are in excess of 25% of the individual's Institutional Base Salary.

Non-financial interests that require disclosure include but are not limited to:

- a. Participation in the research project as key personnel (PI, Co-PI, sub-investigator);
- b. Co-Author on a publication of the research project's results;
- c. Other relationships which may influence judgment of the IRB member in reviewing the research project:
 - i. is a direct supervisor or trainee of the researcher(s)
 - ii. is related to a researcher whose protocol is under consideration
 - iii. has a prominent role in a directly competing research team or product
 - iv. has a close personal relationship with a researcher or for other reasons feels unable to render a fair and unbiased review.

An IRB member or consultant with either a financial or non-financial 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 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

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.

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

21 CFR 56.107 (e)

45 CFR 46.107 (e)

Oklahoma Statutes Citationized, Title 74. State Government

Chapter 62 Appendix – Title 257. Ethics Commission, Article Chapter 20

5. References to Other Applicable SOPs and Policy

303B, IRB Meeting Administration

403, Initial Review – Criteria for IRB Approval.

Individual Conflict of Interest Policy – Health Sciences Center

Institutional Conflict of Interest Policy

6. Attachments

None.

7. Process Overview

7.1 Disclosures

- 7.1.1 IRB members will disclose financial and non-financial conflicts of interests to the IRB as described below.
- 7.1.2 The HRPP Director and IRB Chair shall review disclosures to determine whether a conflict of interest exists and to determine appropriate management of the conflict of interest.
- 7.1.3 IRB members will disclose to the IRB in writing, financial and non-financial conflicts of interests when they are appointed to the IRB. The IRB will remind IRB members to report disclosures to the IRB on at least an annual basis and as needed to reflect changes that add or delete conflicts of interest.

7.2 Prior to a Convened IRB Meeting

- 7.2.1 The IRB Administrator will include a coversheet with each member's meeting packet of items to be reviewed in preparation for each convened IRB meeting. The packet will include the definitions and examples of potential financial and non-financial conflicts of interest. IRB members will be asked to review the packet of items and disclose any potential conflicts of interest relating to any review item included in their packet to

the IRB Administrator or IRB Chair prior to each IRB meeting. Primary and secondary reviewers will be reassigned as necessary to manage conflicts of interests.

7.2.2 In addition, the IRB Administrator will check the agenda prior to the meeting to identify IRB members who may have a conflict of interest due to their participation as key personnel on a current or proposed research project. If a conflict of interest is identified, the study is assigned to another member who does not have a conflict of interest.

7.2.3 An IRB member who has a conflict of interest with regard to a research project that will be reviewed at a convened IRB meeting must notify the IRB office of the conflict prior to the meeting and will recuse him/herself from discussion and voting on that research project. Once the IRB office receives notice of a recusal, the IRB Administrator will seek an alternate IRB member to join the meeting for the review of that project if necessary to meet quorum.

7.3 At the Convened IRB Meeting

7.3.1 At the beginning of each convened IRB meeting, the IRB Chair or designee will ask the members if anyone has a financial or non-financial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The IRB Chair or designee will announce that members with a conflict of interest must recuse themselves from deliberation and voting on that research protocol.

7.3.2 Any IRB member who has a conflict of interest with regard to a research project that will be reviewed at the convened IRB meeting will recuse him/herself from the convened IRB meeting for the discussion and voting on that research project. The HRPP Director or designee will remind the IRB member to recuse him/herself before the review. The recused member can answer questions from the IRB, but cannot be present for IRB deliberations and voting. If the conflict affects quorum, see SOP 303B, IRB Meeting Administration.

7.3.3 The recusal of the IRB member for conflict of interest is recorded in the IRB meeting minutes.

7.4 Expedited Review

7.4.1 IRB members who are conducting expedited review must disclose to the IRB Chair or HRPP Director any conflicts of interest they have related to the study under review, and must not review those items.

7.4.2 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: 07/01/2010

NEXT ESTABLISHED REVIEW DATE: MAY 2012