

SOP: 104A
CONFLICT OF INTEREST - INVESTIGATORS

1. POLICY

All investigators (defined as those responsible for the design, conduct, or reporting of research) shall disclose in writing to the IRB all conflicts of interest for themselves and their spouses, domestic partner, and dependent children. For purposes of this policy, a conflict of interest is an economic interest that could affect or appear to affect the design, conduct, 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. Value 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.

In the absence of compelling rebuttal, an investigator with a conflict of interest in a research project involving human participants may not conduct that research. However, an investigator will have the opportunity to present compelling reasons and circumstances to justify exceptions to this general rule. The IRB will not approve a research protocol where a conflict of interest is neither eliminated nor managed. The IRB has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately.¹

Investigators 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 investigators' relationships with companies that have no influence on the design, conduct, or publication 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 which may be affected by the outcome of the study shall be

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.

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 OU investigators who submit protocols to the OU IRBs.

3. RESPONSIBILITY

A. Investigator Responsibilities

1. Investigators shall disclose to the IRB all conflicts of the investigator, investigator's spouse, domestic partner, and dependent children with regard to a research project involving human participants. Such disclosure shall be in writing, sufficiently detailed, and timely to allow accurate and objective evaluation of the conflict. The investigator shall evaluate whether a conflict of interest exists, and he/she shall disclose any identified conflicts to the IRB, at the following times:
 - a. With the initial IRB application;
 - b. At each continuing review of the project;
 - c. When a conflict of interest arises, as described herein.
2. If the investigator indicates on the IRB Application that a conflict exists, the investigator shall submit the HRPP Conflicts of Interest Disclosure Form.
3. The answers on the Application and the HRPP Conflicts of Interest Disclosure Form shall accurately and completely detail economic relationships with the sponsor or a competitor of the sponsor or other economic interest in the research. Additionally, the principal investigator shall verify whether other key personnel have economic interests as described in this policy and, if so, shall disclose those interests in writing to the IRB.
4. If an investigator discovers that he/she has a conflict of interest during the conduct of a study involving human participants, the investigator shall report the conflict to the IRB in writing within 10 calendar days of the investigator becoming aware of the conflict by submitting an Amendment, including proposed or anticipated changes to the research procedures or informed consent documents to address the conflict of interest, and the completed HRPP Conflicts of Interest Disclosure Form.
5. Investigators 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 or manage the conflict before the IRB will approve the Application or Amendment. In addition, investigators shall assure that all requirements from conflicts of interest reviews are properly incorporated into the corresponding informed consent documents and protocol, as applicable.

B. IRB Responsibilities

1. The IRB, IRB Chair, or IRB chair designate, will review each human research application for disclosure of conflict of interest.
2. The IRB will forward all disclosed conflicts of interest not addressed by this policy to the appropriate University official to be addressed under either the Policy regarding Conflict of

Interest - Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus.

3. The IRB will determine whether the disclosed economic interest is likely to affect or appear to affect the design, conduct, or reporting of the study. Specifically, the IRB will consider the impact of the economic interest on:
 - a. Study design;
 - b. Protocol;
 - c. Informed Consent Form (particularly representations of risks and benefits);
 - d. Data collection and reporting;
 - e. Eligibility determinations and application of inclusion and exclusion criteria;
 - f. Continuing consent;
 - g. Clinical determinations, if applicable (e.g., dose modifications, removing patients from study, related care);
 - h. Determination and reporting of adverse events and their relationship with study mechanism for data and safety monitoring; and
 - i. Data made available to the IRB on continuing review (integrity and sufficient).
4. After a review by the IRB and input by the appropriate vice president, if applicable, the IRB may disapprove research that involves a conflict of interest, or it may approve the research and require changes at the expense of the investigator or sponsor to eliminate or manage the conflict. Required actions may include, but are not limited to:
 - a. Requiring divestiture or termination of relevant economic interest;
 - b. Requiring investigator recusal from a study;
 - c. Altering participation of the investigator in all, or a portion, of the research;
 - d. In case of equity, imposing a bar on insider trading, or requiring the transfer of securities to an independent financial manager or blind trust, or limiting the timing of sales or distributions;
 - e. Monitoring research; i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data);
 - f. Requiring independent clinical review of appropriateness of clinical care given to research participants, if applicable;
 - g. Monitoring the consent process; and/or
 - h. Requiring disclosure of the conflict to institutional committees, research participants, journals, and data safety monitoring boards.
5. In determining the appropriate action, the IRB shall take into consideration any compelling justification presented by the investigator, including, but not limited to:
 - a. The nature of the research;
 - b. The magnitude of the interest or the degree to which the conflict is related to the research;
 - c. The extent to which the interest could affect the research;
 - d. The fact that a specific individual is unique in his/her clinical or scientific qualifications to conduct the research;

- e. The degree of risk to the human participants involved that is inherent in the research protocol; and/or
- f. An effective plan that can be developed to manage the conflict.

4. APPLICABLE REGULATIONS AND GUIDELINES

None.

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

6. ATTACHMENTS

104A-A Conflict of Interest Disclosure Form

7. PROCESS OVERVIEW

7.1 IRB Staff makes sure all documents are reviewed for submission per SOP 301, Research Submission Requirements.

The IRB Administrator makes sure the HRPP Conflicts of Interests Disclosure Form is present and completed if a conflict is indicated on the IRB Application form or Application for Continuing Review.

- 7.1.1 The Administrative Staff conducts preliminary data entry, assigns the appropriate board, and forwards to the IRB Administrator for processing. The IRB Administrator receives new application documents and checks for accuracy of information as well as that all required documents are submitted, including the HRPP Conflicts of Interests Disclosure Form, if applicable. The IRB Administrator makes an initial assessment of the study to determine if it requires review by expedited procedures or a convened IRB. The study is either assigned to the next appropriate agenda or given to the IRB Chair for review.
- 7.1.2 The IRB, IRB Chair, or designee will review each human research application for disclosure of conflict of interest. The IRB will determine whether the disclosed economic interest is likely to affect or appear to affect the design, conduct, or reporting of the study. If the conflict can be managed, the IRB will provide to the investigator a plan. This plan will be documented in the file and in the IRB minutes.
- 7.1.3 The IRB will forward all disclosed conflicts of interest not addressed by this policy to the appropriate University official to be addressed under either the Policy regarding Conflict of Interest - Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus.
- 7.1.4 After review by the IRB and input by the appropriate vice president, if applicable, the IRB may disapprove research that involves a conflict of interest, or it may approve the research and require changes at the expense of the investigator or sponsor to eliminate or manage the conflict.
- 7.1.5 The conflict of interest plan and all communication with University officials will be documented in the file. Discussion at the convened meeting regarding the conflict and plan will also be documented in the IRB minutes.

APPROVED BY: _____

DATE: 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012