SOP 104A: CONFLICTS OF INTEREST IN HUMAN PARTICIPANT RESEARCH

1. POLICY

The purpose of this policy is to provide an overview for identifying, disclosing, and managing conflicts of interest so that the rights and welfare of human participants in research, the integrity of human participant research, and the credibility of the Office of Human Research Participant Protection (HRPP) is not compromised by outside institutional interests or obligations or by individual conflicts of interest. The IRB is concerned with the processing of disclosures of conflicts of interest involving human participant research and how it is managed in order to ensure there are adequate protections in place for human participants.

1.1 Institutional Conflict of Interest Policy

Institutional conflicts of interest can occur whenever the external financial interests or business relationships of the University or one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct review or oversight of the University's research. It is the policy of the University that all institutional conflicts of interest, whether real or perceived, must be fully disclosed. The reported conflict must be properly identified and either managed or eliminated prior to initiating any contract, sponsored project, dedicated gift, or transaction that might appear to be influenced by the conflict. The institutional policy is implemented using a three-step approach: 1) disclose always, 2) assess the potential for institutional conflicts of interest, and 3) manage the conflict in most cases, and prohibit the activity when necessary to preserve the University's mission or protect the public's interest.

The University maintains an Institutional Conflict of Interest Policy that covers departments most likely to be involved in an institutional conflict of interest (Research, Technology Development, Development) and individuals who are authorized to act on behalf of the University (Board of Regents members, Executive Officers). The policy, which is available on the HSC Office of the Vice President for Research website, provides a detailed description of the process to disclose and identify conflicts of interest including what information to disclose, who must disclose, and how to disclose.

1.2 Individual Investigator Conflict of Interest Policy

1.2.1. The protection of human subjects in research requires a process to handle conflicts of interest involving Investigators so that the results of the research are free from bias or the appearance of bias. 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 (COI) that will provide the opportunity for economic gain and external commitments that relate to, or could be reasonably affected by, the outcome of the human subjects research. Disclosures shall be made of all COI for Investigators, their staff, spouses / domestic partners, and dependent children. A list of examples of required disclosures may include but are not limited to:

- anything of monetary value, received or held by an Investigator or their family member, whether or not the potential value that can be readily determined, including but not limited to salary or payment for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works);
- equity interests (e.g., stocks, stock options, or other ownership interests);

- intellectual property rights and interest (e.g., patents, trademarks, service marks, and copyrights);
- positions such as Director, Trustee, Scientific Officer, or member of the Board of Directors, and other related interests or activities of the Investigator that could possibly affect or perceive to affect the results of the research;
- any other financial interest or relationship with an entity related to the research that involves the sponsor, product, or service being tested.

1.2.2. Significant financial interest consisting of one or more of the following interests of the Investigator or research staff (and their spouse, domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities must be reported to the IRB and to the VPR in accordance with affiliated campus COI policy:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. (For purposes of this definition, remuneration includes salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to pubic prices or other measures of fair market value);
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interests;
- In addition to the above requirements, for Public Health Services (PHS) sponsored studies, Investigators must also disclose to the IRB the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value might not be readily available) related to the institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

For examples of strategies to manage financial conflicts of interest, refer to the appropriate COI policies: Policy Regarding Conflict of Interest – Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus.

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. Although the Vice President for Research (VPR) has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately, the IRB may elect not to approve a human research project where it believes a COI is not eliminated or managed.

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 human research project and that occur prior to the initiation of a sponsored human research project 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 human research project 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.)

1.2.3. For VA research projects, in addition to adhering to the above, Investigators who are VA employees or hold a VA appointment shall adhere to the requirements of the VA Office of General Counsel, Office of Government Ethics and comply with all applicable VA and other federal requirements regarding conflict of interest.

2. SCOPE

This SOP applies to all University Investigators who submit human research projects to the University IRBs.

3. RESPONSIBILITY

3.1 **Senior Vice President & Provost**

For Institutional conflict of interest, the Senior Vice President & Provost for each University campus is responsible for collecting and maintaining the applicable information on an annual basis in accordance with the University Institutional Conflict of Interest in Research Activities Policy. The monitoring and enforcement of institutional conflicts of interest are detailed in that policy.

All records related to disclosures and management of COI are maintained according to COI policies: Policy Regarding Conflict of Interest – Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus, and SOP 304: Documentation, Documents, and Data Management.

3.2. **Individual Investigator**

3.2.1 Investigators shall disclose to the IRB conflicts of the Investigator, Investigator's spouse / domestic partner, and dependent children with regard to a research project involving human participants on an annual basis.

The Investigator shall evaluate whether a conflict of interest exists or may exist, and shall disclose any such conflicts to the IRB at the following times:

a. Concurrent with the IRB submission;
b. At each continuing review of the project;
c. When a conflict of interest arises, as described herein;
d. Within 30 days of acquisition or discovery of financial interests

3.2.2 Additionally, the Principal Investigator shall verify whether other key study personnel may have a conflict of interest as described in this policy and, if so, shall disclose those interests, as well.

3.2.3 If the Investigator suspects that a conflict exists, the Investigator shall report this when submitting the IRB submission materials.

3.2.4 If an Investigator discovers that any member of the research team has a conflict of interest during the conduct of a research project involving human participants, the Investigator shall report the conflict to the IRB in writing within 30 calendar days of the Investigator becoming aware of the conflict by submitting a Modification/Notification request to the IRB, describing proposed or anticipated changes to the human research procedures or informed consent documents to address the conflict of interest..

3.2.5. Each Investigator and/or research staff member is responsible for completing the education requirements related to financial conflicts of interest. Education pertaining to conflict of interest follows the requirements set forth in SOP 102B: Key Study Personnel Education. Investigators shall also follow University policy for University-required COI training at the designated intervals per campus policy.

3.2.6. Investigators and/or research staff are responsible for complying with all COI policies and their implications. Sanctions for failure to comply with COI policies may include, without restriction, reprimand, restitution, loss of pay, suspension, or dismissal.

3.2.7. If the Investigator is a VA employee, the Investigator shall adhere to the VA Office of General Counsel Office of Government Ethics, as well.

3.3 **Institutional Review Board**

3.3.1 It is not the purview of the IRB to reinterpret institutional conflict of interest policies or their implementation. Rather the IRB's function is to ensure that participant protection, the integrity of IRB review, and the conduct of a research project are not jeopardized by an undisclosed, unidentified or unmanaged conflict of interest.

3.3.2 The IRB, IRB Chair or IRB designee, will review each IRB submission for disclosure of a COI.

When reviewing human research projects that include a VPR approved COI management plan, in determining the appropriateness of the management plan for research participant protection, 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

3.3.3 The IRB may require additional participant protections in the management plan such as, but not limited to:

a. Requiring divestiture or termination of relevant economic interest;
b. Requiring Investigator recusal from a human research project;
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.
i. After a review of the COI determination by the appropriate VPR, the IRB may elect to disapprove research that the IRB believes involves a conflict of interest that cannot be managed. In this situation, the IRB may consult with the VPR and the Investigator on how to revise the COI management plan to address the human subjects research concerns.

3.3.4. For VA research projects, the IRB shall advise the VA facility of any conflict of interest issues that occur related to a VA Investigator and of any management plans implemented.

4. APPLICABLE REGULATIONS AND GUIDELINES

None

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

6. ATTACHMENTS

University Institutional Conflict of Interest in Research Activities Policy
Health Sciences Center Faculty Handbook – Appendix E
Norman Campus Faculty Handbook – section 5.10
Norman Campus PHS Funding-Specific Conflict of Interest Policy

7. PROCESS OVERVIEW

7.1 Investigators who have a potential conflict of interest shall indicate the conflict on the initial application for research involving human subjects and complete and submit the HRPP Conflict of Interest Disclosure Form to the IRB for review. If the conflict has been disclosed to the VPR and a management plan is available, the Investigator shall also include this information with the IRB submission.

7.2 IRB Staff conducts a pre-review of all documents for submission per SOP 301: Research Submission Requirements. If the IRB application indicates there is a COI, IRB staff confirms that the HRPP Conflict of Interest Disclosure Form is included with the submission materials.

7.3. During pre-review of a research submission, the IRB staff shall forward the HRPP Conflict of Interest Disclosure Form to the VPR or designee to be addressed under either the Policy regarding Conflict of Interest - Health Sciences Center or the Financial Conflicts of Interest Policy – Norman Campus, as appropriate.

7.4 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 interest is likely to affect or appear to affect the design, conduct, or reporting of the study. If the IRB determines that the conflict can be managed, the IRB will provide to the Investigator a management plan. This management plan shall be documented in the file and in the IRB minutes.

7.5 IRB staff shall communicate IRB findings and management plan to the Vice President for Research (VPR) or designee. If the VPR or designee has additional concerns, the VPR will inform the Investigator and provide a copy of communication to the IRB. If additional changes pertain to the research, the Investigator shall submit a modification to the IRB.

7.6 IRB final approval of a research submission is contingent upon concurrence from the VPR or designee.

7.7 The IRB may elect to disapprove the management plan approved by the VPR and require the Investigator submit a revised management plan.

7.8 The COI management plan and all communication with University officials will be maintained in the IRB electronic information system.

APPROVED BY: _____ DATE: 12/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016