University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #6	**TITLE: Investigator Conflict of Interest/OSPA/IRB/ORI Coordination**		**Page 1 of 6**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-05-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: OSPA Director	Signature	Date	Revision Date: 08-30-2017

OBJECTIVE:

To describe the policies and procedures for identifying and managing any significant financial interest held by University of Kentucky (UK) Investigators (as defined below) that could affect research involving human subjects

GENERAL DESCRIPTION:

The University of Kentucky (UK) is committed to conducting all research activities in accordance with the highest standards of integrity and ethics. Institutional regulations (AR 7:2 Financial Conflicts of Interest in Research) set forth principles, policies, and procedures to ensure that Investigator financial interests do not compromise the objectivity with which the Investigator designs, conducts, and reports the research. These regulations apply equally to all research whether the study is funded or non-funded. The Office of Sponsored Projects Administration (OSPA) is the central administrative unit that administers the UK individual conflict of interest policy.

The UK Institutional Review Board (IRB) has established procedures to coordinate with OSPA and to ensure that Investigator financial interests do not affect the rights and welfare of human subjects in research. IRB policy requires that Investigators report all significant financial interests on each study to the IRB for review to assure protection of the rights and welfare of human subjects participating in research.

DEFINITIONS

Investigator, as defined by AR 7:2 Financial Conflicts of Interest in Research, means the project director or principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research.

A potential or actual Conflict of Interest (COI) exists when a significant financial interest (as defined below) of an Investigator or an immediate family member of the Investigator could directly and significantly affect the design, conduct, or reporting of research. Immediate family is defined as a spouse or dependent child.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of an Investigator or family member that reasonably appears related to the individual's institutional responsibilities:

- 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;
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity during the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator or family member holds any equity interest in the entity;
- A significant financial interest includes any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- For an Investigator who applies for or receives funding through a Public Health Service (PHS) grant, cooperative agreement, or contract, a significant financial interest includes any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities. Excluded is 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 medical center or a research institute that is affiliated with an institution of higher education.

The term, for human subjects research, does *not* include:

- Salary or other remuneration from UK;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency;
- Income from service on advisory committees or review panels for a federal, state, or local government agency.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #6-8 Revision #5	**TITLE: Investigator Conflict of Interest/OSPA/IRB/ORI Coordination**	**Page 3 of 6**

RESPONSIBILITY:

Execution of SOP: Investigators (as defined above), IRB, Office of Research Integrity (ORI) staff, ORI Director, Office of Sponsored Projects Administration (OSPA) Conflict of Interest Administrator (COIA), OSPA Director, Research Conflict of Interest Committee (RCOIC) , Institutional Official (IO; i.e. Vice President for Research)

PROCEDURES

Disclosure Requirements for Externally-funded Research

1. All UK Investigators conducting externally-funded research must complete the online Financial Disclosure Statement (FDS), disclosing any significant financial interest, prior to submission of a proposal for external funding, as defined in AR 7:2 Financial Conflicts of Interest in Research. The Investigator must complete an FDS at least annually or within 30 days of acquiring a new financial interest that reasonably appears related to his or her institutional responsibilities.
2. The FDS contains questions designed to determine whether the Investigator or anyone in his/her immediate family has significant financial interests which could impact the objective pursuit of the research.
3. The PI completes education about disclosures and responsibilities related to financial conflicts of interest each year when completing the annual disclosure, or if an Investigator is found to be noncompliant with the regulation, or if the regulations change researcher requirements.
4. The PI completes the questions regarding disclosure of financial interest in the IRB application. The PI also polls all other Investigators involved with the project and asks them if there is a financial conflict of interest. The PI completes the questions based on financial interest of all investigators involved with the project.
5. If the PI indicates in the IRB application that there is a significant financial interest and it relates to the project, the ORI notifies the OSPA COIA and requests a Conflict of Interest Management Plan.
6. The Institutional Official (IO) or designee reviews the completed FDS and refers any potential financial conflict of interest to the appropriate University official, i.e., the college dean, center director, or senior administrator.

Disclosure Requirements for Non-funded and Internally-Funded Research

1. If the study is not funded or internally-funded, the Principal Investigator (PI) may not have completed the FDS prior to IRB submission.

2. The PI conducting non-funded or internally-funded research completes the questions regarding disclosure of financial interest in the IRB application. The PI also polls all other Investigators involved with the project and asks them if there is a financial conflict of interest. The PI completes the questions based on financial interest of all investigators involved with the project.

3. If the PI answers the question indicating that he/she or another investigator involved with the project has a significant financial interest requiring disclosure, the PI or the investigator with the conflict completes the online FDS.

4. The ORI notifies the OSPA COIA that the Investigator has disclosed a significant financial interest in the IRB application. The OSPA COIA contacts the Investigator to initiate the process described in AR 7:2.

5. The Investigator must complete an FDS at least annually or within 30 days of acquiring a new financial interest that reasonably appears related to his or her institutional responsibilities.

6. The PI completes education about disclosures and responsibilities related to financial conflicts of interest each year when completing the annual disclosure, or if an Investigator is found to be noncompliant with the regulation, or if the regulation changes researcher requirement**s.**

Review of Disclosures and Management of Conflicts

1. The IO or designee reviews the FDS to assess whether or not the significant financial interest constitutes a financial conflict of interest. The IO or designee may involve the Investigator in the determination of whether a disclosed significant financial interest is related to the Investigator's research.

2. If the review reveals that the disclosed significant financial interests do not represent a financial conflict of interest, the determination is recorded and no further action is required.

3. If a potential financial conflict of interest exists, the IO or designee notifies the Investigator and the appropriate dean or director.

4. The dean or director reviews the FDS along with the Investigator to determine if the Investigator can eliminate the conflict. If the Investigator can eliminate the conflict, the dean or director provides a written copy of the agreement to the IO or designee and, if the IO or designee approves the plan, no further action is needed.

5. If the Investigator cannot eliminate the conflict, the Investigator proposes a plan to manage or reduce the conflict. If the research involves human subjects, the Investigator must design the plan so that the financial interest does not affect the risk to or welfare of research subjects. The IO or designee reviews the plan and refers the case to the Research Conflict of Interest Committee (RCOIC) for review.

6. The RCOIC may accept the recommended plan, add to it, or create a new plan. As outlined in AR 7:2, the RCOIC has broad discretion to recommend a variety of conditions to manage, reduce, or eliminate the conflict. The RCOIC sends its recommendations to the IO.

7. The IO may accept the recommendation or modify the proposed plan. The IO makes the final decision to approve a management plan.

8. If the research involves human subjects, the OSPA Director or designee is responsible for forwarding a copy of the final approved management plan to the ORI.

IRB Review of the Approved Management Plan

1. The IRB does not complete its review and approval of the IRB application until it receives the final approved management plan. Upon receipt of the plan from OSPA, ORI staff send the plan to the appropriate IRB. The IRB reviews the plan using either the convened IRB or expedited procedures based upon whether the study is eligible for expedited review.

2. The IRB determines whether the conditions in the approved plan for managing the financial interest adequately protect the rights and welfare of human subjects or whether additional actions are necessary to minimize the risks to subjects. The IRB determines the kind, amount, and level of detail of information the PI must provide to subjects in the informed consent process regarding source of funding, funding arrangements, financial interests of parties involved in research, and any techniques applied to manage financial COI.

3. The IRB has the final authority to decide whether the interest and management, if any, allows the research to be approved. The IRB may impose further restrictions on the protocol or disapprove the protocol. The IRB does not have the authority to disapprove the final IO approved management plan but may require additional protections for human subjects before the research can be initiated.

Sponsor-Investigator Clinical Trials

If the PI is also considered the sponsor who holds an investigational new drug (IND) or an investigational device exemption (IDE), he/she follows Food and Drug Administration (FDA) requirements for reporting financial disclosures as outlined in 21 CFR 54.

REFERENCES:

Department of Health and Human Services Final Guidance Document, *Financial Relationships and Interest in Research Involving Human Subject: Guidance for Human Subjects Protection*
Public Health Service 42 CFR 50 Subpart F
National Science Foundation Grants Policy Manual Section 510
Food and Drug Administration 21 CFR 54
AR 7:2 Financial Conflicts of Interest in Research