

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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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: 11-06-09

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 II-4.0-4) 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 sponsored, i.e., funded by an external organization, or non-sponsored. 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 II-4.0-4, is the principal investigator, a co-principal investigator, and any other person at the University who is responsible for the design, conduct, or reporting of research.

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A potential or actual Conflict of Interest (COI) exists when a significant financial interest (as defined below) of an Investigator, a family member of the Investigator or an associated entity, would reasonably appear to affect the research activities of the Investigator or the development of intellectual property.

Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), financial interest in the sponsor, product or service being tested, and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). For research involving human subjects, “Significant Financial Interest” also includes employee or executive relationships with entities that have a financial interest in the research even when no remuneration is involved.

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

- Salary or other remuneration from UK;
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- Income from service on advisory committees or review panels for public or non-profit entities.

RESPONSIBILITY:

Execution of SOP: Investigators (as defined above), IRB, Office of Research Integrity (ORI) staff, the ORI Director, Office of Sponsored Projects Administration (OSPA) Conflict of Interest Administrator, OSPA Director, Research Conflict of Interest Committee (RCOIC), Vice President for Research (VPR)

PROCEDURES

Disclosure Requirements for Externally Funded Research

1. All UK Investigators conducting externally funded research must complete a Research Financial Interest Disclosure Statement (RFIDS) prior to submission of a proposal for external funding, disclosing any significant financial interest, as defined in AR II-4.0-4 Research Conflict of Interest and Financial Disclosure Policy.
2. The RFIDS 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 Investigator submits the completed RFIDS to the appropriate University official, i.e., the college dean, center director, or senior administrator.

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4. If the answer is "yes" to ANY of the questions on the RFIDS, the Principal Investigator includes a copy of any applicable RFIDS in the IRB application,
5. Investigator must update disclosures, for as long as the research is ongoing, any time a new relevant significant financial interest develops or is acquired.

Disclosure Requirements for Non-externally Funded Research

1. If the study is non-sponsored, the PI will not have completed the RFIDS prior to IRB submission.
2. The PI conducting non-sponsored research completes the IRB's Disclosure of Financial Interest Form – Form Y and includes it with his or her IRB application submission.
3. If the PI answers "yes" to ANY of the questions in Section 1 of Form Y, he/she must attach a description of the safeguards that he/she will put in place to ensure that the financial interest does not inappropriately impact recruitment of subjects and the informed consent process.
4. The PI also polls all other Investigator involved with the project and asks them to answer all questions on the RFIDS. The PI signs the form certifying that he/she has done this. The PI instructs any Investigator who answers "yes" to any of the questions to complete a RFIDS. The PI includes the form with the IRB application.
5. The ORI notifies the OSPA COI Administrator that the PI has disclosed a significant financial interest. The OSPA COI Administrator contacts the Investigator to initiate the process described in AR II-4.0-4.
6. The Investigator submits the completed RFIDS to the appropriate University official, i.e., the college dean, center director, or senior administrator.
7. Investigator must update disclosures, for as long as the research is ongoing, any time a new relevant significant financial interest develops or is acquired.

Review of Disclosures and Management of Conflicts

1. The University official reviews the disclosure along with the Investigator to determine if the Investigator can eliminate the conflict. If the Investigator can eliminate the conflict, the University official notifies OSPA and the VPR, and no further action is needed.
2. 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

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the plan so that the financial interest does not affect the risk to or welfare of research subjects. The University official reviews the plan and forwards it to OSPA.

3. OSPA checks the disclosure and plan for completeness and forwards it to the Research Conflict of Interest Committee for review.
4. The RCOIC may accept the recommended plan, add to it, or create a new plan. As outlined in section VIII.C.4., of AR II-4.0-4, the RCOIC has broad discretion to recommend a variety of conditions to manage, reduce, or eliminate the conflict. The RCOIC sends its recommended plan to the VPR.
5. The VPR may accept the recommendation or return the matter to the RCOIC with concerns or suggestions. The VPR makes the final decision to accept a management plan.
6. If the research involves human subjects, the OSPA Director is responsible for forwarding a copy of the final VPR 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 VPR 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 VPR approved management plan but may require these additional protections.

Sponsor-Investigator Clinical Trials

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

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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 II-4.0-4 Research Conflict of Interest and Financial Disclosure Policy