Financial Conflict of Interest in Research Policy

Policy Title:

Financial Conflict of Interest in Research Policy

I. Policy Statement

The purpose of this policy is to protect the credibility and integrity of the University of Pikeville's (UPIKE) faculty and staff and to ensure public trust and confidence in the university's research and educational activities. These policies and procedures are designed to meet the requirements of Federal regulations covering Investigator financial conflicts of interest (42 CFR Part 50 Subpart F for grants and cooperative agreements and 45 CFR Part 94 for contracts). UPIKE has a responsibility to manage, reduce, or eliminate any identified financial conflicts of interest that may arise because of the financial interests of an Investigator.

II. Definitions

Financial Conflict of Interest (FCOI) exists when UPIKE, through its university official or official designee, reasonably determines that an Investigator's Significant Financial Interest is related to a federally funded research project (i.e., the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the federally funded research.

Institutional Official (IO) means the individual at UPIKE who is responsible for the review of disclosures of significant financial interest. The IO has authority to suspend all relevant activities until the financial conflict of interest is resolved or mitigated.

Institutional Responsibilities means teaching, research consultation and institutional committee memberships.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the Federal sources, or proposed for such funding, which may include, for example, collaborators and consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge.

Senior/key personnel means the principal investigator and any other person identified as senior/key personnel by UPIKE in the sponsored research application, progress report, or any other report submitted to the funding agency.

Financial interest means all financial interests that have monetary value, whether the value is readily ascertainable.

Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    a. Regarding any publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, when aggregated, exceeds $5,000.
    b. Regarding any non-publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator holds any equity interest in the entity.
    c. Intellectual property rights and interests, upon the receipt of income exceeding $5,000 related to such rights and interests (not reimbursed by UPIKE)
2. The occurrence of any reimbursed or sponsored travel exceeding $5,000 undertaken by the Investigator and related to the Investigator's institutional responsibilities. It includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. The disclosure agreement excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes that are affiliated with U.S. institutions of higher education.

The term Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties or other reimbursement paid by UPIKE to the Investigator, if the Investigator is currently employed or otherwise appointed by UPIKE, including intellectual property rights assigned to UPIKE and agreements to share in royalties related to such rights.
- Income from investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decision making.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Note, disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. Investigators must disclose all foreign financial interests received from any foreign entity when such income meets the threshold for disclosure ($5,000).

III. Training Requirements

A. Training Requirements for a Federal Sponsor

1. UPIKE Investigators must complete FCOI training prior to engaging in research related to any Federally funded grant or contract, at least every four years, and immediately under the following circumstances:
   a) University FCOI policies change in a manner that affects Investigator requirements.
   b) An Investigator is new to UPIKE; or
   c) UPIKE finds an Investigator noncompliant with this FCOI policy or management plan.

2. To meet the training requirement, Investigators must review this policy and successfully complete CITI training.

3. UPIKE will notify each proposed Investigator seeking federal funding of this policy, the Investigator's disclosure responsibilities, and the Federal regulation.

B. Training Requirements Specific to NIH
   1. See sections III. A.1. and III. A.3. above.

2. To meet the NIH training requirement, Investigators must review this policy and complete successfully the NIH FCOI Training Module found at FCOI Training|grants.nih.gov.

IV. Disclosure, Review, and Monitoring Requirements

A. Investigator Disclosures

1. Investigators are required to complete a Significant Financial Interest Disclosure form as follows:
   a. Prior to submission of a proposal to a federal funding agency.
   b. Annually for federally funded grants: In January of each calendar year, Investigators are required to complete an updated Significant Financial Interest Form.
   c. Within 30 days of discovering or acquiring a new Significant Financial Interest.
   d. Investigators joining UPIKE who are conducting research sponsored by federal funding agencies to which this policy applies will provide all necessary disclosures within 30 days.

2. Using UPIKE's SFI Disclosure Form, each Investigator will disclose their foreign and domestic SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

3. Disclosures of travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The IO or an official designee will determine if additional information is needed to determine whether the travel constitutes an FCOI regarding the Investigator's research. The initial disclosure of reimbursed or sponsored travel should include income received over the previous 12 months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

B. Review of Disclosures

The IO or an official designee will review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI prior to the expenditure of any funds and determine whether an FCOI exists. An FCOI exists when the University, through its IO or official designee,

reasonably determines that an Investigator's SFI is related to a Federally funded research project based on the criteria below:

- The SFI could be affected by the research or
- The SFI is in an entity whose financial interest could be affected by the research and
- The SFI could directly and significantly affect the design, conduct, or reporting of the Federally funded research.

C. Management Plans

If the IO or official designee, with the assistance, if necessary, of appropriate members from Financial Operations, determines that there is an FCOI, the IO or official designee must approve a written management plan to manage, reduce, or eliminate the conflict before any related research commences. Such plans will be designed to meet applicable legal requirements, facilitate the resolution or management of any conflict, and protect the sensitivity of disclosed information. The affected Investigator is responsible for developing and submitting a proposed management plan to, and in consultation with, the IO or an official designee. The IO or an official designee will provide a final determination regarding the management plan. Management plans may impose any condition and prescribe any action necessary to manage, reduce, or eliminate actual or potential conflicts of interest, including but not limited to the following:

1. Public disclosure of the FCOI in presentations and publications.
2. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias.
3. Modification of the research plan.
4. Disqualification from participation in all or a portion of the research.
5. Divestiture of SFIs; or
6. Severance of relationships that create actual or potential conflicts.

V. Enforcement and Non-Compliance

A. Non-compliance

1. Whenever an Investigator has failed to comply with this policy or an FCOI management plan, the University will within 120 days review and determine whether the non-compliance could have biased the design, conduct, or reporting of the research. If bias is found, the University will promptly notify the Federal funding agency and submit a mitigation report.

2. The University may take appropriate action regarding the Investigator's employment status or other disciplinary action.

3. In the case of PHS-funded research, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of PHS-funded research, the University must promptly notify the PHS awarding component of the corrective action taken or to be taken.

VI. Public Disclosure of FCOIS

For PHS-funded research, the University will provide public access to information about FCOIs held by senior/key personnel via the University's website or by written response to any requestor within five business days of a request. The information must include:

- Investigator's name, title, and role with respect to the research project.
- The name of the entity in which the SFI is held.
- The nature of the SFI; and
- The approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

VII. Recordkeeping

The University will maintain records relating to all Investigator disclosures of financial interests and the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI) and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the Federal funding agency or from other dates specified in 45 CFR 75.361, where applicable.

VIII. Subrecipient Requirements

If any part of the Federally funded research is carried out through a subrecipient (e.g., subcontractors or consortium members), UPIKE must incorporate, as part of a written agreement with the subrecipient, terms that establish whether the FCOI policy of UPIKE or that of the subrecipient will apply to the subrecipient's Investigators.

1. If the subrecipient's investigators are subject to the subrecipient's FCOI policy, the subrecipient must certify as part of the agreement that its policy complies with the applicable Federal regulations (42 CFR 50, Subpart F). If the subrecipient

cannot provide such certification, the agreement must state that subrecipient Investigators are subject to the FCOI policy of UPIKE for disclosing SFIs that are directly related to the subrecipient's work for the University of Pikeville.

2. If the subrecipient's Investigators must comply with UPIKE's FCOI policy, the agreement must specify the time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to UPIKE. Such time period(s) must be sufficient to enable UPIKE to comply timely with its review, management, and reporting obligations under Federal regulations.

IX. Related Institutional Policies

Related institutional policies include the Code of Conduct, Research Misconduct Policies and Procedures.

X. Contact Information

For questions regarding this policy, please contact:

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Responsible Divisions/Offices: Academic Affairs; Office of Advancement
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