

## **POLICY TITLE:**

**Financial Conflict of Interest in Research** 

## **APPLIES TO:**

All faculty, staff, students, and collaborators participating in sponsored projects and those individuals responsible for designing, conducting, or reporting research or educational activities funded by external sources.

## **ADMINISTRATIVE AUTHORITY:**

Office of Research & Innovation
Sponsored Programs
Office of the Provost and Vice President of Academic & Student Affairs

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**EFFECTIVE DATE:** 

**NEXT REVIEW DATE:** 

#### **POLICY STATEMENT:**

The purpose of this policy is to ensure that all research and sponsored program activities conducted under the auspices of Kentucky State University (KSU) are free from actual or potential bias resulting from financial conflicts of interest. This policy promotes transparency and objectivity in research, protects the integrity of KSU and its researchers, and ensures compliance with all applicable federal regulations, including 42 CFR Part 50 Subpart F (Public Health Service) and 45 CFR Part 94 (National Science Foundation).

# **DEFINITIONS:**

## Conflict of Interest Committee (COIC)

The institutional committee, appointed by the President or his or her designee, responsible for reviewing significant financial interest disclosures and determining whether a financial conflict of interest exists.

# Financial Conflict of Interest (FCOI)

A significant financial interest that could directly or significantly affect the design, conduct, or reporting of sponsored research.

## **Institutional Responsibilities**

An investigator's professional responsibilities on behalf of KSU, including but not limited to research, research consultation, teaching, professional practice, and service on institutional committees.

## **Investigator**

Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by an external sponsor. This includes the principal investigator (PI), co-investigators, and any other key personnel.

## Significant Financial Interest (SFI)

A financial interest consisting of one (1) 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:

- With regard to any publicly traded entity: An SFI exists if the value of any remuneration received from the entity in the twelve (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: An SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator holds any equity interest.
- **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- **Sponsored or reimbursed travel:** For PHS-funded investigators, the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities.

A significant financial interest does not include: salary, royalties, or other remuneration paid by KSU; income from investment vehicles, such as mutual funds, over which the investigator does not exercise control; income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency or an institution of higher education; or income from service on advisory committees or review panels for a U.S. federal, state, or local government agency or an institution of higher education.

## **PROCESS:**

#### **Disclosure of Significant Financial Interests**

All investigators are required to complete and submit an SFI disclosure form to the Office of Research & Innovation (ORI):

- At the time of proposal submission to any external sponsor.
- Annually, for the duration of a sponsored award.
- Within thirty (30) days of discovering or acquiring a new SFI.

This disclosure must include all SFIs related to the investigator's institutional responsibilities.

## **Review and Management of Conflicts**

KSU's Conflict of Interest Committee (COIC) will review all SFI disclosures. If the COIC reasonably determines that an SFI constitutes a financial conflict of interest (FCOI), KSU will, in collaboration with the investigator, develop and implement a written conflict management plan (CMP) before any related sponsored funds may be expended. The CMP will specify actions to be taken to manage, reduce, or eliminate the FCOI.

Examples of conditions or restrictions that might be imposed in a CMP include:

- Public disclosure of the FCOI in presentations and publications.
- Modification of the research plan to mitigate the conflict.
- Appointment of an independent monitor to oversee the research.
- Disqualification from participation in the portion of the project related to the FCOI.

## **Training Requirements**

All investigators must complete FCOI training:

- Prior to engaging in sponsored research.
- At least once every four (4) years.
- Immediately, if KSU revises this policy, an investigator is new to KSU, or an investigator is found to be non-compliant with this policy.

# **Subrecipient and Collaborator Compliance**

KSU will take reasonable steps to ensure that any subrecipient, contractor, or collaborator on a KSU-administered sponsored project complies with federal FCOI regulations. This will be achieved by establishing a written agreement that requires the subrecipient to either certify that its own FCOI policy is compliant with federal regulations or agree to abide by this KSU policy.

# **Public Accessibility**

In accordance with federal regulations, KSU will make information concerning identified FCOIs held by senior/key personnel on PHS-funded projects publicly accessible upon written request.

## **Non-Compliance and Enforcement**

Failure to disclose an SFI in a timely manner or to adhere to a mandated CMP constitutes non-compliance with this policy. Non-compliance may result in administrative sanctions, loss of eligibility to participate in sponsored projects, and/or other disciplinary action. In cases of confirmed non-compliance involving PHS-funded research, KSU will conduct a retrospective review and submit a mitigation report to the PHS as required by regulation.

#### **Record Retention**

ORI shall retain all SFI disclosures, FCOI reviews, CMPs, and related documents for a period of at least three (3) years from the date of submission of the final expenditures report for the applicable sponsored project.

## **REFERENCES AND RELATED MATERIALS:**

- 42 CFR Part 50, Subpart F: Promoting Objectivity in Research
- 45 CFR Part 94: Responsible Prospective Contractors
- NSF Proposal & Award Policies & Procedures Guide (PAPPG), Chapter IX.A
- Institutional Ethics and Code of Conduct

## **CONTACTS:**

Subject	Office	Telephone	E-mail
General Questions	Sponsored Programs	(502) 597-5837	Dorothy.Daley@kysu.edu
& Disclosures			

# **HISTORY**:

Revision Type	Date of Issuance/Revision	Drafter(s)/Editor(s)
Issued (New Policy)	June 2025	Dorothy Daley and Zach Atwell