

Financial Conflict of Interest Training for Investigators

Objectives

- Define conflicts of interest or “COIs”.
- Describe the investigator’s responsibility regarding conflicts of interest and reporting of significant financial interests.
- Explain the institution’s responsibility regarding COIs and how it impacts the investigator.
 - For example, identifying, reviewing, managing and reporting conflicts of interests

KUMC Policy Statement

KUMC's COI [policies and procedures](#) assure compliance with The Kansas Board of Regents policy and requirements applicable to research conducted under the auspices of KUMC.

This includes research subject to

- Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)
- Other publicly funded research
- Industry funded research, and
- Non-externally funded research

42 C.F.R. Part 50, Subpart F Promoting Objectivity in Research

Purpose:

The federal regulation cited above promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Note: The existence of a COI does not mean that an activity is inappropriate. However, COI's must be recognized, disclosed and properly managed (or eliminated where appropriate).

Who is an Investigator?

Consistent with the PHS regulation, "Investigator" means the project director or principal investigator and other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research which may include, for example, collaborators or consultants.

NIH states:

- Institutions should consider the role, rather than the title, of those involved in research and degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases

Investigator Responsibility

- Know KUMC's COI [policies and procedures](#)
- Complete COI training as required
- Disclose Significant Financial Interests (SFIs) to KUMC at the applicable time: 1) before proposal submission; 2) annually, and 3) **updates within 30 days.**
- Comply with management plans issued by KUMC

What is an SFI that Requires Disclosure?

- It is a “financial interest” of the covered person, or his or her immediate family (spouse, dependent children) and personal household, that *reasonably appears to be related* to his or her responsibilities on behalf of the university, e.g., teaching, research, administration, professional practice, committee memberships, e.g., IRB participation.
- It does **not** include sources such as salary from KUMC or UKP, income from mutual funds and retirement accounts (as long as there is no direct control of the investment decisions made in these vehicles) or income from certain government or educational entities for activities like seminars or lectures.

What is an SFI that Requires Disclosure?

More specifically, an SFI is a financial interest that reasonably appears related to responsibilities on behalf of the University, and consists of:

- a) An interest in any **publicly traded entity**, if the value of **Remuneration** received in the 12 months preceding disclosure, and the value of any **Equity Interest** as of the date of disclosure, when aggregated **exceeds \$5,000**; or
- b) An interest in any **non-publicly traded entity**, if the value of **Remuneration** received in the 12 months preceding the disclosure, when aggregated, **exceeds \$5,000**, or when the Covered Person holds **any Equity Interest**; or
- c) **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests. It does not include income paid by the University or KUIC on behalf of the University.
- d) **Reimbursed or sponsored travel** (other than from federal, state or local governmental agencies, institutions of higher ed as defined in 20 USC 1001(a); and academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher ed).

When does the SFI need to be disclosed?

- No later than the time of the application for PHS funding
- Within 30 days of discovering or acquiring a new SFI
- At least annually during the period of the award
- Before joining an on-going PHS-funded research project
- At time of application to the IRB and IACUC.
 - Refer to the COI questions in the IRB and IACUC applications.

Additional Considerations

- Certain non-PHS sponsors have adopted these requirements and require KUMC to comply with them.
- Sponsors of FDA regulated research are required to obtain financial disclosures. These requirements are in addition to KUMC requirements and may differ in reporting threshold and other stipulations.
- Certain federal agencies that sponsor research may have different requirements (Department of Defense, National Science Foundation)

Training

An investigator must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional financial conflict of interest policies change in a manner that affects Investigator requirements.
- An investigator is new to an institution.
- An institution finds that an investigator is not in compliance with the institution's policy or management plan.

Institutional Responsibilities

Institutional responsibilities include:

- Maintaining an up-to-date, written, enforced PHS compliant policy on financial conflicts of interest.
- Designating an institutional official to solicit and review disclosures.
- Requiring investigators to disclose at the appropriate time, e.g., at the time of application for PHS funded research, annually.
- Determining whether disclosures of SFIs are “**financial conflicts of interest**”.

Financial Conflict of Interest

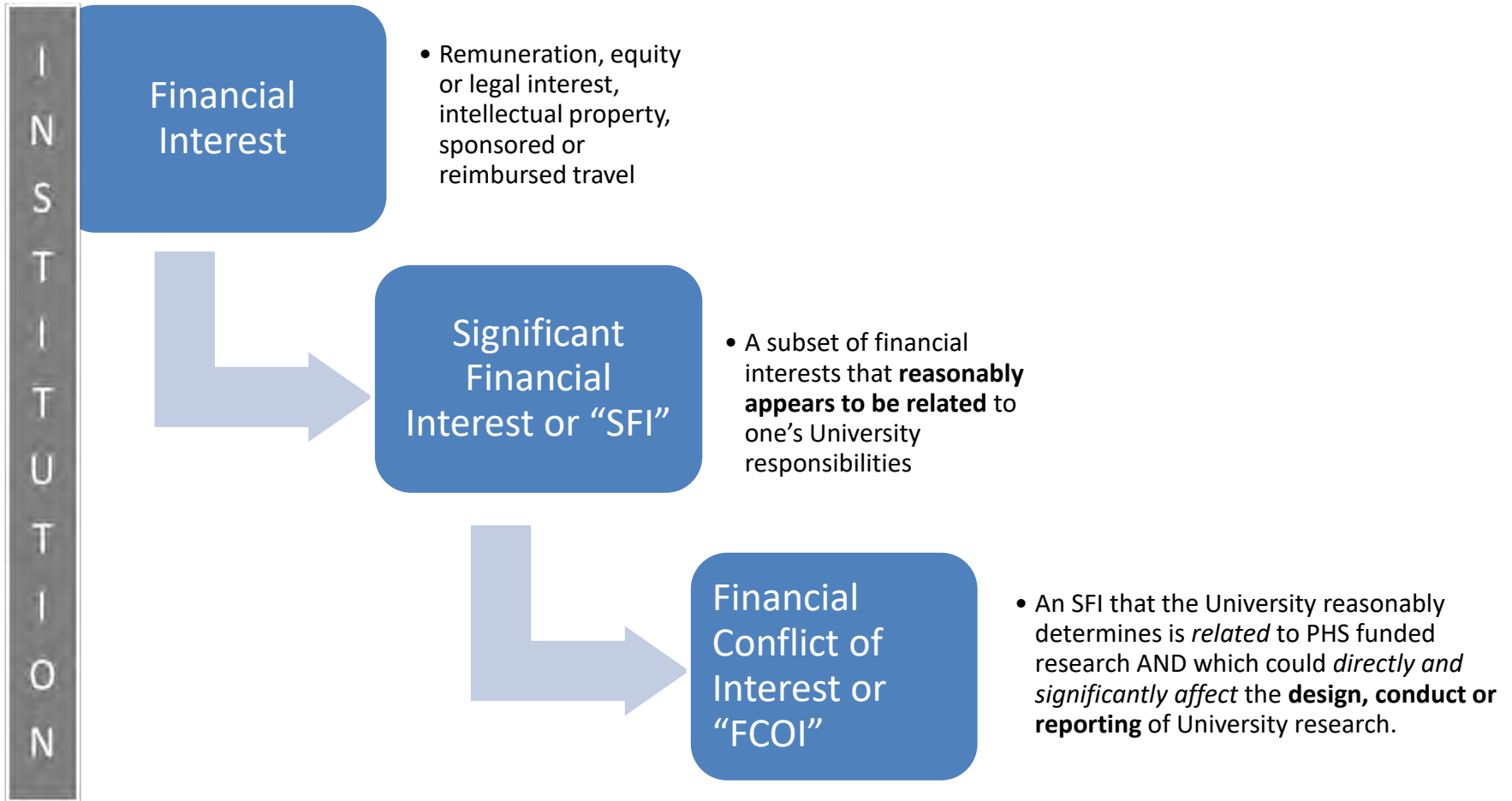
A “financial Conflict of Interest” or “FCOI” is defined as:

A Significant Financial Interest that KUMC reasonably determines compromises or has the appearance of compromising the fulfillment of professional duties; teaching, clinical or scientific judgement; integrity of research data and the research; or the safety and welfare of patients and/or research subjects. In the case of research, this includes a Significant Financial Interest that KUMC reasonably determines could directly and significantly affect the design, conduct or reporting of KUMC research.

Disclosure Review and Management

- KUMC must determine whether any of an investigator's SFIs are related to the research. That is, whether the SFI could be affected by the PHS funded research; or is in an entity whose financial interest could be affected by the research. Then, KUMC must determine whether that related SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- If it is determined that both of these conditions are present, an FCOI exists.
- If an FCOI determination is made, prior to the expenditure of any research funds the institution is required to develop and implement a management plan to reduce or eliminate the FCOI.

Financial interest in relation to an FCOI



How Disclosures are Reviewed

- Disclosures are reviewed by the Office of Compliance, COI Program.
- They are referred to the COI Committee if a possible conflict is identified.
- The COI Committee determines if a conflict exists and approves a management plan.
- COI staff facilitates communication with the IRB or IACUC regarding the management plan.
- The IRB or IACUC may impose its own requirements.

How COI's are Managed

COI staff provide the management plan to the faculty/staff member for review, comment and acceptance.

Examples of management strategies include:

- Public disclosure (or disclosure to participants)
- Appointment of independent monitor
- Modification of the research plan
- Change of personnel or responsibilities
- Reduction or elimination of the financial interest

Timely disclosure and Retrospective Review

If an SFI is not disclosed in a timely manner or if KUMC fails to review a previously existing SFI during an ongoing PHS-funded project:

- KUMC, shall within 60 days of the determination of noncompliance, review the SFI; determine whether it is related to the PHS-funded research; and determine whether a Financial Conflict of Interest exists. If an FCOI exists, the institution will implement, on at least an interim basis, a conflict management plan that will specify the actions that have been or will be taken to manage the FCOI and submit an FCOI report to the PHS funding agency.

Retrospective Review and Mitigation Reporting Requirement

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Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose;
- Failure by KUMC to review or manage such FCOI; or
- Failure by the Investigator to comply with an conflict management plan;

KUMC must, within 120 days of the determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

Required FCOI Reports to be Provided to NIH Through eRA Commons FCOI Module

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Report	Content	Required When?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

Public Accessibility

Prior to the KUMC's expenditure of any funds under a PHS-funded research project, KUMC shall ensure public accessibility, via written response within five business days of a request, of information concerning any SFI disclosed to the Institution that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted ;
2. The Institution determines that the SFI is related to the PHS-funded research; and
3. The Institution determines that the SFI is a Financial Conflict of Interest.

KUMC Responsibilities regarding Sub-recipients

- When grant sub-recipients can certify that they have in place a policy and process consistent with the PHS regulation, KUMC will rely on the sub-recipient to solicit and evaluate disclosures of its personnel, manage any related conflicts and report details to KUMC.
- Where that is not the case, KUMC will require non-employed investigators to disclose and certify through the applicable campus procedure and forms.
- Similarly, KUMC will provide other institutions with necessary certifications and information when KUMC is acting as a sub-recipient on a grant.

Federal Guidance

NIH FCOI Website:

<http://grants.nih.gov/grants/policy/coi/>

- Final Rule
- Frequently Asked Questions

FDA: Guidance for Clinical Investigators, Industry, and FDA Staff, Financial Disclosure by Clinical Investigators

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

KUMC Policies and Procedures*

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- University of Kansas Individual Conflict of Interest Policy
- KUMC Conflict of Interest Procedures
- Management of Inventor Conflict of Interest Policy
- Employment of Students and Residents in Faculty-Owned Businesses
- KUMC Institutional Conflict of Interest Policy

*All KUMC Conflict of Interest policies are available at:

<https://www.kumc.edu/office-of-integrity-and-compliance/conflict-of-interest/policies-and-procedures.html>