Division of Research Administration
FINANCIAL CONFLICT OF INTEREST IN RESEARCH

Basics of Financial Conflict of Interest in Research

Manager of Financial Conflict of Interest
What is Financial Conflict of Interest in Research?

“Financial Conflict of Interest means a financial interest of an investigator that could directly and significantly affect the design, conduct, or reporting of the investigator’s research or research-related educational activities.”

Saint Louis University Conflict of Interest in Research Policy
Version 4.1, October 29, 2012
Why do Financial Conflicts of Interest Arise?

- Conflicts are common in research institutions.
  - Pharmaceutical and biotechnology companies rely on academic institutions for research and development of their products.
  - Investigators are often engaged by companies to give lectures, do consulting work, and serve on advisory boards due to their expertise.

- Conflicts may exist despite the highest standards of conduct.
Financial conflicts of interest may be perceived as compromising:
- Research integrity
- Student education
- Protection of human subjects

Financial conflicts of interest, real or perceived, can damage institutional, personal, and professional reputations.

Consequences of undisclosed or poorly managed conflicts can be severe.
Who Cares about Financial Conflicts of Interest?

• Saint Louis University

• Federal Agencies
  – Public Health Service (NIH, CDC, etc.)
  – National Science Foundation
  – Other federal sponsors

• Media and public officials

• The general public
SLU’s Financial Conflict of Interest in Research Policy

• **Purpose:**
  - Protect SLU ethical standards
  - Protect investigator reputation
  - Maintain research integrity

• Complies with federal regulations

• Provides information to investigators, staff, and students regarding their responsibilities
If I Disclose, Will I get in Trouble?

Disclosing a financial conflict of interest does not imply wrongdoing or automatically preclude investigators from receiving research awards.

BUT…

Undisclosed conflicts can result in serious consequences including loss of research funding and other serious penalties.
The Financial Conflict of Interest in Research Policy applies to all (including faculty members, adjunct instructors, research associates, research assistants, professional staff members, administrators, consultants, collaborators, contractors, students, and others) involved in the design, conduct, and reporting of research and research-related educational activities.
Key Changes to FCOI Policy (prior to 8/24/2012)

• Mandatory FCOI Training
• Lower Threshold Disclosure
• Mandatory Travel Disclosure
• Required Annual and Amended Disclosures
• All Researchers (regardless of pay or role)
Financial Conflict of Interest in Research Policy

All individuals involved in research who have not submitted an annual disclosure must do so prior to the submission of a proposal to any external funder.
Who is required to submit a FCOI disclosure?

- All SLU faculty, staff, students and other trainees (regardless of pay) listed on an application and/or award for external research funding (includes Adjunct and/or Emeritus faculty);

- **All listed Non-SLU senior/key personnel** (regardless of pay) listed on an application and/or award for external research funding (*if listed as senior/key personnel*, may include Co-Investigators, consultants, and collaborators); and

- All other Non-SLU individuals responsible for the design, conduct, or reporting of research (if a Non-SLU individual is not identified as senior/key personnel, then the Principal Investigator must determine whether the Non-SLU individual is responsible for the design, conduct or reporting of research).
What do I need from Non-SLU Researchers?

Saint Louis University’s Office of Research Integrity must be in receipt of all Non-SLU Disclosures prior to the submission of any external application for research funding and before award funds are disbursed.
Non-SLU Researchers - Subaward

If a Non-SLU researcher will be part of a subaward agreement, then the subcontractor can provide written documentation indicating whether to use its own policy. Satisfactory documentation includes one of the following:

- A [Letter of Intent to Establish a Consortium Agreement](#); or

- A signed letter from the authorized institutional official acknowledging (1) the institution has a COI policy that conforms to 45 CFR Part 94 and 42 CFR Part 50, Subpart F, (2) the listed collaborator is in compliance with such policy, and (3) the listed collaborator will be monitored for FCOI and reported to SLU within 30 days of participation on the research project of any identified FCOI(s) related to the award.
When do I use a Non-SLU COI Disclosure Form?

A Non-SLU COI Disclosure Form is required prior to the submission of any external application for research funding and before award funds are disbursed if:

- A Non-SLU researcher is involved on the project without the issuance of a subaward; or
- A subcontractor elects to comply with SLU’s COI policies and procedures.

FCOI training will also be required at the time of award.
What Happens after I Submit a Disclosure?

• Positive disclosures are reviewed by the Conflict of Interest Committee.

• Review process is based on compliance with SLU’s FCOI policy and federal regulations.

• Disclosures are treated confidentially.
What is the Review Process for Disclosures?

- Disclosures are considered on a case-by-case basis.
- Grant funds cannot be expended until all potential conflicts have been managed, reduced, or eliminated.
- Review process is conducted in a manner that is intended to foster, not hinder research relationships.
What If I Don’t Want to Do It?

Any faculty, staff, or student engaged in research who does **NOT** submit a COI disclosure or who does **NOT** comply with COIC rulings are referred to the Vice President of Research for corrective action.
Financial Conflict of Interest in Research Resources

• SLU COI website at: http://www.slu.edu/x25241.xml
  - COIR policy
  - COICR policy
  - Disclosure form
  - FAQ’s
  - Contact information

• NIH COI website at: http://grants.nih.gov/grants/policy/coi/

• AAMC COI website at: http://www.aamc.org/research/coi/start.htm
Contact Information

For any questions regarding Financial Conflict of Interest, contact:

COI@SLU.EDU

Manager of Financial Conflict of Interest
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