Basics of Conflict of Interest in Research

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What is Conflict of Interest in Research?

“Conflict of interest means a situation in which a significant financial interest of an investigator could directly and significantly affect the design, conduct, or reporting of the investigator’s sponsored or educational activities.”

Saint Louis University Conflict of Interest in Research Policy
Version 3.0, August 1, 2009
Why do 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.
Why Are Conflicts of Interest Important?

• Conflicts of interest may be perceived as compromising:
  - Research integrity
  - Student education
  - Protection of human subjects

• 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 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 Conflict of Interest in Research Policy

- Policy accessed at: http://www.slu.edu/x27916.xml

- 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
What are Significant Financial Interests?

• Personal compensation >$10,000 in a calendar year
  -or-
• Company ownership/Equity >$10,000 or >5% ownership (regardless of net value)
  -or-
• Other financial considerations

*Financial interests include those of the investigator, his/her spouse, and dependent children.
• Salary, royalties, or other remuneration from SLU.

• Payments from governmental or non-profit organizations for seminars, lectures, service on advisory committees or review panels.

• Investment income from mutual funds or blind trusts.
Examples of Situations Requiring Disclosure

- Investigator receives consulting fees of $15,000 from a company that sponsors his/her SLU research.

- Investigator holds stock valued at $150,000 which is 6% interest in a company whose products he/she uses in research.

- Investigator’s spouse is the CEO of a company sponsoring the investigator’s SLU research.
Who Must Disclose?

• Any SLU employee involved in the design, conduct, or reporting of research:
  - Faculty
  - Staff
  - Students
All externally funded research requires financial disclosure.
Disclosing a 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.
What is the Process for Disclosure?

- **Form accessed at:** [http://www.slu.edu/x27916.xml](http://www.slu.edu/x27916.xml)

Disclosures must be completed, signed by the individual and their department chair, and submitted to Sara Stanley at Fusz Hall.
What Are the Disclosure Requirements?

• All SLU employees engaged in research must submit a disclosure at the beginning of each calendar year.

• Disclosures must be filled out accurately, completely, and on the current calendar year form.

• Incomplete or incorrect forms will be sent back for revision.

• When submitting a proposal through eRS, investigators who have not filed an annual disclosure must do so before their proposal can be submitted.

• A new disclosure must be filed within 30 days if investigator’s financial situation changes from their previous submission.
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 COI 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 Does the Committee Look For?

- Could the financial interest affect the design, conduct, or reporting of the research?

- What is the potential impact on the research, the investigator, and the institution?

- How are students affected?

- Is the protection of human subjects addressed sufficiently?

- Are University facilities and resources used appropriately?
How Are Conflicts Managed?

- Goal is to enable the research to proceed.

- Conflict management plans may include:
  - Disclosure in publications and presentations.
  - Excluding the investigator, staff, or student from parts of the research.
  - Modification of the research protocol.
  - Monitoring or oversight of research by a third party.
  - Divestiture of financial interests.
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 Provost for corrective action.
COI Reporting Requirements

• Public Health Service (PHS):
  - All conflicts and assurance of management must be reported prior to expenditure of agency funds.
  - Conflicts must be reported within 60 days of disclosure.

• National Science Foundation (NSF):
  - Only unmanaged conflicts must be reported.
Conflict of Interest in Research Resources

- SLU COI website at: [http://www.slu.edu/x27916.xml](http://www.slu.edu/x27916.xml)
  - COIR policy
  - COICR policy
  - Disclosure form
  - Conflict level chart and case studies
  - FAQ’s
  - Contact information


- AAMC COI website at: [http://www.aamc.org/research/coi/start.htm](http://www.aamc.org/research/coi/start.htm)
Future Directions

• Electronic COI disclosure system:
  - Faster.
  - Easier.
  - More comprehensive.
  - Will address additional areas of conflict outside of research (institutional, clinical)
  - All faculty and staff will be required to complete yearly disclosure, regardless of research status.
  - Built into eRS system.
  - Rollout in 2010.
Contact Information

For any questions regarding conflict of interest, contact:

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