Conflict of Interest Training
2019
What is a Conflict of Interest (COI)?
Why does COI management matter? What are the risks?
What about Conflicts of Commitment?
What should I do with my potential COI? Disclose it!
How will my potential COI be reviewed and managed?
WHAT IS A CONFLICT OF INTEREST?

What is a COI

COI Risks

Conflicts of Commitment

Disclosure

Review and Management
WHAT IS A CONFLICT OF INTEREST?

- Conflicts of Interest: circumstances that create a risk that professional judgements or actions regarding a primary interest will be unduly influenced by a secondary interest.
  - Primary Interests: promoting and protecting the integrity of research, the quality of medical education, and the welfare of patients.
  - Secondary Interests: financial interests; pursuit of professional advancement and recognition; and the desire to do favors for friends, family, students, or colleagues.
COI RISKS

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Review and Management
• Patients and the public benefit when different players in the healthcare industry collaborate to coordinate care and develop new products for treatment.

• It is beneficial for SIU SOM when faculty and employees are viewed as experts and have opportunities to appropriately collaborate with industry.

• However, secondary interests can unduly influence professional judgment or create bias, threatening the integrity of research, the quality of patient care, the objectivity of professional education, and the public’s trust in medicine. Additionally, some opportunities may be kickbacks in disguise.
WHY DOES COI MANAGEMENT MATTER? WHAT ARE THE RISKS?

• A Drug Company Manager admitted that he and sales representatives induced physicians, advanced practice nurses, and physician assistants to prescribe Subsys by paying them for sham “Speaker Programs.”

• The Manager told one provider that the more Subsys prescriptions the provider wrote, the more Speaker Programs the company could provide.

• Speaker Programs were held at high-end restaurants and gathered licensed providers with the ability to prescribe to tell them about the drug.

• “Speakers” were paid several thousand dollars for attending these dinners.
WHY DOES COI MANAGEMENT MATTER? WHAT ARE THE RISKS?

• Lincare, a DME company, paid $10 million and signed a Corporate Integrity Agreement to settle kickback and self-referral allegations.
  
  • OIG alleged that Lincare gave referring physicians sporting and entertainment tickets, rounds of golf, fishing trips, advertising expenses, office and medical equipment, golf equipment, meals, and gift certificates.
  
  • The kickbacks came disguised as payments for consulting agreements (e.g., Medical Director Agreements).
WHY DOES COI MANAGEMENT MATTER?
WHAT ARE THE RISKS?

- IL University Faculty Research and Consulting Act
- Anti-Kickback Statute
- Stark Law/Physician Self-Referral Law
- IL State Officials and Employees Ethics Act
- Physician Payment Sunshine Act
- IL Governmental Ethics Act
- HHS and FDA Human Subject Protection COI guidance and regulation
- PHS/NIH Grant FCOI regulations
- SIU COI Processes
WHY DOES COI MANAGEMENT MATTER? WHAT ARE THE RISKS?

The goal of SIU SOM COI policies, processes, and management is to protect the integrity of professional judgment, protect patients, and preserve public trust.
EXAMPLES OF TYPES OF CONFLICTS OF INTEREST

• Financial Conflicts of Interest
• Clinical Conflicts of Interest
• Research Protocol-Specific Conflicts of Interest
• CPE-Related Conflicts of Interest
• Gifts and Entertainment
• Interested Fiduciary Transactions & Self-Dealing
• Adverse Interest in a Supplier or Competitor
• Usurping Corporate Opportunities
• Academic Conflicts of Interest or Intellectual Bias
CONFLICTS OF COMMITMENT

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WHAT ABOUT CONFLICTS OF COMMITMENT?

• A conflict of commitment arises when the external activities, whether compensated or not, of an SIU SOM employee are so demanding of time or attention, or are so closely related to the employee’s SIU work, that they interfere with the individual’s primary responsibilities to the SIU SOM.

• Conflicts of commitment must also be disclosed for review and management through the COI process.
WHAT ARE EXAMPLES OF POTENTIAL COI THAT I SHOULD DISCLOSE?

- Consulting
- Research outside SIU
- Secondary employment/adjunct faculty appointments
- Ownership interests in competitors or vendors of SIU
- Honoraria for presentations, speaking engagements
- Remuneration (gifts, conference fees, travel) from outside SIU
- Grant or manuscript review
- Board membership

NOTE: all paid activities must be approved PRIOR to activity commencement; unpaid activities should be reported within 30 days of activity commencement
WHAT SHOULD I DO WITH MY POTENTIAL COI? DISCLOSE IT!

- Disclose it and get preapproval.

- Annual and intermittent (as needed) COI disclosures are submitted through the COI module link at https://siu.imedris.net.

- Directions for submitting an annual disclosure, or updating the annual disclosure with intermittent disclosures are found https://siumed.edu/compliance.

- Note: Potential COI that are started without preapproval may be rejected and may leave the requestor subject to discipline.
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CONSIDERING COI RISK

- **Influence**
  - Minimal Influence
  - Physician, Purchasing, Contracting, C-suite, Board, etc.

- **Type of Relationship**
  - Unpaid/Volunteer
  - Paid Consulting/Research
  - Investment
  - Ownership

- **Type of External Organization**
  - Government
  - Academic
  - Non-Profit
  - For Profit/Industry

- **Value of Remuneration**
  - No Remuneration (£)
  - Low (£)
  - Medium (₦)
  - High (₦₦)

- **Relative Similarity to SIU Role**
  - Completely Unrelated
  - Very Similar

- **Risk of Reputational Harm**
  - Lower Risk of Harm if it went public
  - Higher Risk of Harm if it went public

- **Time Needed for Activity**
  - Minimal Amount of Time
  - Moderate Amount of Time
  - Significant Amount of Time
HOW WILL MY POTENTIAL COI BE REVIEWED AND MANAGED?

• **Review**: Your potential COI will be reviewed by the Office of Compliance and Ethics. Factors considered will include type of activity, source of remuneration, amount of remuneration, similarity to SIU role, etc.

• **Low Risk Administrative Approval**: If your COI is deemed low risk and does not require a management plan, your request may be administratively approved by the Office of Compliance and Ethics.
HOW WILL MY POTENTIAL COI BE REVIEWED AND MANAGED?

• **Medium and High Risk COI:** If your COI is deemed more than low risk, the Office of Compliance and Ethics will discuss with the Office of General Counsel, Subject Matter Experts, and the COI Faculty Liaison. This team will consider whether the potential COI is manageable, and if so, will work with you and your department chair on a management plan to help monitor the relationship and prevent misconduct.

• **Unmanageable COI and Decision Appeals:** Not all disclosed COI will be manageable. If the activity presents too much risk to SIU, the COI activity may be disallowed. The discloser may bring denial appeals and management plan concerns to the Executive Compliance Committee.
ADDITIONAL COI RESOURCES

- Office of Compliance and Ethics COI Resource page

- Office of Compliance and Ethics
  - compliance@siumed.edu
  - 217-545-4248

- External Compliance Hotline and Online Reporting Tool
  - 1-800-910-6707
  - [http://www.siumed.edu/compliance/reporting-suspected-compliance-issues-or-concerns.html](http://www.siumed.edu/compliance/reporting-suspected-compliance-issues-or-concerns.html)