Executive Committee Conflict of Interest Training

March 4, 2019



CONFLICT OF INTEREST TRAINING OBJECTIVES





- 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?







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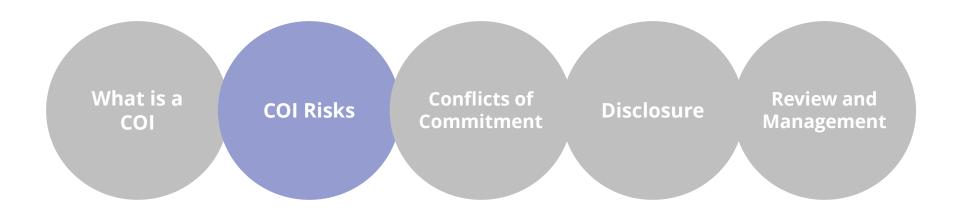


- Conflicts of Interest: circumstances that create a risk that professional judgements or actions regarding a primary interest will be unduly influenced by a secondary interest.
 - Primary Interests: promoting and protecting the integrity of research, the quality of medical education, and the welfare 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









- 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.





- 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.



- 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).





- State and Federal laws may apply to certain types of COI
 - Stark Law
 - Anti-Kickback Statute
 - Illinois Governmental Ethics Act and the State Officials and Employees Ethics Act
 - University Faculty Research and Consulting Act





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



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







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 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.



DISCLOSURE







WHAT SHOULD I DO WITH MY POTENTIAL COI? DISCLOSE IT!



- Disclose it and get preapproval.
 - Note: Activities that are started without preapproval may be rejected and may leave the requestor subject to discipline.
- Annually, all faculty and employees must disclose all potential conflicts of interest and commitment through the COI iMedRIS module (Coming soon-details to follow).
- Intermittently and BEFORE beginning any potential activity (i.e., outside employment, consulting), disclose opportunities that arise during the year to the COI Committee for review (coiadministration@siumed.edu).
 - Note: Once built, disclosers with intermittent potential conflicts will access the COI iMedRIS module to update their current disclosure with the new information.

REVIEW AND MANAGEMENT







HOW WILL MY POTENTIAL COI BE REVIEWED AND MANAGED?



- Review: Your potential COI will be reviewed by a team including the Office of Compliance and Ethics, an Associate General Counsel, and a faculty member who is the Chair of the COI Committee.
- Administrative Approval: If your COI is deemed low risk and does not require a management plan, your request may be administratively approved with COI Committee notification at the next meeting.



HOW WILL MY POTENTIAL COI BE REVIEWED AND MANAGED?



 <u>COI Management</u>: If your COI is deemed moderate risk but may be managed, the team will work with you, your department chair, subject matter experts as needed, and the COI Committee to develop a management plan to help monitor the relationship and prevent misconduct.



PROPOSED CHANGES TO COI MANAGEMENT AT SIU SOM



- The current COI process at SIU SOM has been assessed and several changes are underway.
- COI will go through the Office of Compliance and Ethics, and will be collaboratively reviewed and managed, as appropriate, with Legal, the discloser and his/her chair, subject matter experts, and a faculty liaison.
- New draft tools to help with COI management: disclosure form,
 COI review criteria, management plan template, workflow, policy, education.
- More information forthcoming in your inbox and on the Office of Compliance and Ethics intranet.



COI TRAINING



QUESTIONS?



THANK YOU!



Additional questions? Contact us!

- Office of Compliance and Ethics
 - compliance@siumed.edu
- External Compliance Hotline and Online Reporting Tool
 - 1-800-910-6707
 - <u>http://www.siumed.edu/compliance</u>
- Sarah Couture
 - Interim Compliance Management; <u>scouture45@siumed.edu</u>
- Brenda D. Pryor
 - Associate General Counsel; <u>bpryor86@siumed.edu</u>

