

Helping Your Department Head and Faculty to Manage Conflict of Interest Issues

Bringing Administrators Together Conference

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- **Overview: Goals/Objectives**

- Recognize the importance of disclosing and managing conflicts of interest (COI).
- Recognize situational factors that can give rise to potential or actual conflicts of interest.
- Identify university, state and federal policies or regulations relating to conflicts of interest.
- Identify and articulate methods of managing conflicts of interest.
- Provide practical tips and tools on how to better coach your department head and faculty on COI issues.
- Work effectively with university forms and processes for disclosing and managing conflicts of interest.

- **Overview: Topics**
 - Background COI info
 - Policies and regulations
 - Annual and transactional disclosures
 - Effectively managing conflicts
 - Maximizing efficiency with forms and processes.

- **What is individual COI? (1 of 2)**

- “A ‘conflict of interest’ arises when an academic staff member is in a position to influence either directly or indirectly University business, research, or other decisions in ways that could lead to gain for the academic staff member, the staff member's family, or others to the detriment of the University's integrity and its missions of teaching, research, and public service.”

- "Family" is defined as one's spouse and children.

- *University of Illinois Policy on Conflict of Commitment and Interest*

- **What is individual COI? (2 of 2)**
 - COI resides in a situation, not in an individual's behavior.
 - Whether the conflict is “Real,” “Apparent,” “Potential, or “Perceived,” it must be *managed*.
 - For reporting and review purposes, conflicts of commitment only occur during the contract period; ***conflicts of interest can occur beyond the contract period.***

- **Significant Financial Conflicts of Interest**
 - In connection with federally funded research, federal regulations define “significant” as:
 - financial interests in business enterprises or entities that exceed \$10,000, or
 - financial interests in business enterprises or entities that represent more than 5% ownership.
 - *Note that the dollar value represented by >5% ownership is irrelevant.*

- **Why pay attention to COI?** (1 of 3)
 - Generating Benefits for *individuals* and the *institution*
 - Maximizing Credibility
 - Ensuring Objectivity
 - Maintaining Public Trust
 - Guarding our Reputation
 - Protection & Safety
 - Risk Management

- **Why pay attention to COI?** (2 of 3)
 - Avoiding Harms for *individuals* and for the *institution*
 - Sanctions
 - Increased vulnerability
 - Resource allocation
 - Ramifications

- **Why pay attention to COI?** (3 of 3)
 - Federal funding requires a written and enforced COI policy.
 - State agencies/entities are concerned that our policy be adequate, and properly monitored/enforced.
 - Compliance with University policies is included in terms of employment.

- **COI and the Unit Head**

- According to policy, the Unit Head holds ***primary responsibility*** for working with the academic staff member to manage conflicts.
 - “It is incumbent upon the academic staff member and the unit executive officer to manage or resolve real or apparent conflicts.”
 - The COI officer and the Ethics officer are additional resources

- **Annual & Transactional Disclosures**
 - Annual Reports of Non-University Activities (RNAUA)
 - Proposal Approval Form (PAF)
 - IRB Form
 - Office of Technology Management (OTM)

- **Should people be reluctant to disclose conflicts?**
 - Never be reluctant to disclose a real or apparent COI!
 - A conflict itself is not necessarily bad, but an unmanaged conflict can be devastating.
 - Most “real” and probably all “apparent” conflicts can be managed.

- **RNUA Questions**

- Consulting/other financial relationship with sponsor of research
- Fiduciary responsibility/consulting with company doing business with University or in field of research
- External activities involving other University personnel
- Any other potential conflicts?

- **Unit Head Role/Responsibilities** (1 of 3)
 - Unit heads hold primary responsibility to manage COI/COC
 - Communicate to employees that they need to participate and direct employees on where to get the forms and information
 - Ensure all faculty and other academic staff participate fully
 - Adhere to procedures and timeline
 - Emphasize “request for prior approval” as opposed to mere “reporting”

- **Unit Head Role/Responsibilities** (2 of 3)
 - Careful review of RNUA forms as they are turned in each fall, and as updated forms are received during the year
 - Discussions and follow up questions with academic staff as needed regarding reported and possibly unreported activities
 - Verify that other employees named in activities have also disclosed, if required to report
 - Allow an employee to respond if activities are not approved before forwarding the form to the next level of review.
 - Prepare form for files if the employee cannot do so

- **Unit Head Role/Responsibilities** (3 of 3)
 - Reinforce the need to update the form if external activities change
 - Monitor compliance throughout the academic year
 - Acknowledge sanctions for noncompliance
 - Acknowledge that compliance with university policies is included in terms of employment

- **IRB and PAF Questions**
 - Ownership/fiduciary responsibility with sponsor
 - Consulting with sponsor
 - Gift funds from sponsor
 - Ownership/fiduciary responsibility with subcontractee
 - Any other potential conflicts?
 - Is sponsor a faculty company?

- **COI Statement of Explanation and Management (SEAM) form**
 - Describe the nature of the conflict.
 - Describe the conflicted person's role and function in the study.
 - Provide justification for the conflicted person's involvement in the study.
 - Describe the conflict management techniques.

www.research.uic.edu/conflict

- Click the link to “Manage Conflicts”
- Click the link to “Preparing COI Statements for PAFs and IRB Protocols.”

- **OTM**
 - Disclosure of discoveries
 - Licensing
 - CMP required prior to licensing to faculty start-up company

- **How can COI be managed?** (1 of 3)
 - IRB, COI, OTM, ORS, work together.
 - Resolution is situation-specific
 - Guidelines for handling similar situations
 - Resolution *always* begins with disclosure
 - Resolution may involve a combination of conflict management techniques.

- **How can COI be managed?** (2 of 3)

- **Management Techniques:**

- Independent review
- Disclosure of conflict in publications, presentations, etc.
- Disclosure of conflict to other research personnel (e.g., co-investigators, fellows, students)
- Conflicted person not involved in data collection
- Conflicted person not involved in data entry
- Conflicted person not involved in data analysis
- Dataset given to independent statistician for comparison
- Analysis of existing data (are the data de-identified?)
- Investigator-initiated study
- Non-conflicted individuals involved in study development (design, conduct, analysis)

• How can COI be managed? (3 of 3)

– Management Techniques (for Human Subjects Research):

- Conflicted person will not solicit informed consent (will conflicted person identify potential research participants but then direct these people to a non-conflicted individual for the consenting process?)
- Implementation of an independent DSMB or data monitoring board
- Monitoring board has a priori rules (e.g., safety and efficacy) for stopping the study
- Multi-center trial. (What percent of the total study population will be enrolled at UIC? Will it be no more than 10% of the national projected enrollment?)
- Double-blind or triple-blind design
- Protocol involves standard level of care
- Disclosure of conflict in consent form
- Minimal risk to research subjects
- Increased frequency of continuing review by IRB

- **University Ethics Office (1 of 2)**
 - **Policies**
 - Code of Conduct
 - Whistle-blower Policy
 - Reporting and Investigation of Fraud
 - Gifts to Employees
 - **Legislation**
 - State Officials and Employees Ethics Act
 - Illinois Governmental Ethics Act
 - Statements of Economic Interests
 - Gift Ban Act

- **University Ethics Office** (2 of 2)
 - **Donna McNeely**, University Ethics Officer
 - Toll Free Help Line: 866-758-2146
 - ethicsofficer@uic.edu
 - <http://www.ethics.uillinois.edu>

- www.research.uic.edu/conflict
 - RNUA
 - Forms and Instructions
 - Managing Conflicts
 - Preparing COI Statements for PAFs and IRB Protocols
 - How Can Conflicts of Interest be Managed?
 - What is the Process for Completing a Conflict Management Plan?
 - What is the Process for Completing a CMP-Annual Report?
 - Educational Resources
 - Conflict Review Committee
 - Policy
 - University
 - State
 - Federal

- **Conflict of Interest Office**

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