

Conflict Of Interest Issues:
*What You Don't Know
Could Hurt You*

University of California
2013 Compliance and Audit Symposium

**Conflict of Interest (COI)
Laws and Policies**

- Today's presentation is a brief overview of a limited number of COI requirements and issues.
- COI Rules are complex and fact-specific: Small change in facts may result in change of advice.
- When in doubt, seek advice.

Examples of COI Laws and Policies (1)

- Political Reform Act
- Public Contract Law and Code
- Fair Political Practices Commission (FPPC) regulations
- University COI Code
- Incompatible Activities law

Today's presentation will only summarize a small portion of these COI requirements.

Examples of COI Laws and Policies (2)

- UC Standards of Conduct
- UC Statement of Ethical Values
- Employee-Vendor Relationship policies
- Conflict of Commitment or Outside Activities policies
- Patent and Licensing policies
- Campus policies

- And many more.....

COI Laws and Policies

- Prohibit public employees from personally benefitting at the expense of the public interest.

- Cover financial interests of employee and family members.

- Consider the *appearance* of conflict in the decision-making process.

COI Context

- Making a University decision – voting on a matter, appointing someone, entering into a contract
- Participating in making a University decision – giving advice or making recommendations to decision-maker
- Influencing a University decision – communications with any UC person for the purpose of influencing the decision

Economic Interests

- Business entities
- Real property
- Sources of Income
- Sources of Gifts
- Interest in income, expenses, assets, or liabilities (Personal Financial Effects Rule)

COI Laws Are Based Upon:

1. Disclosure
 - Form 700 and 700Us are available to the public.
 - Forms are routinely requested by the media and other interested parties.
2. Recusal
 - Disqualify yourself from decision

Which University Employees are Affected by COI Laws?

- All employees (disqualification, other policies)
- Specific administrative positions (disclosure of financial interests, Form 700)
- Specific academic research positions (disclosure of financial interests, Form 700U)

The Political Reform Act

- “No public employee shall make, participate in making or in any way attempt to use his or her official position to influence a governmental decision in which he/she knows or has reason to know that he/she has a financial interest.” (Gov’t Code § 87100).
- Requires public agencies to adopt a COI Code for employees

COI Disqualification Rule

- University employees should disqualify themselves from making, participating in making, or influencing University decisions if it is reasonably foreseeable that the decision will have a material financial effect on the employee’s economic interests.
- Applies to all University employees and Regents

Resources for COI Questions

- Campus and UCOP COI Coordinators <http://www.ucop.edu/ogc/coi/coord.html>
- UCOP Office of General Counsel (factsheets) <http://www.ucop.edu/general-counsel/legal-resources/index.html>
- Ethics Training <http://ucop.edu/ethics-compliance-audit-services/index.html>

Examples of Possible COI "Red Flags"

- Negotiating public/private partnerships
- Post-employment
- Non-University income/Outside activities
- Free tickets (events, plane)
- Waived conference fees
- Free meals

University's COI Code

- Identifies 1700+ employees who make or influence University decisions that could affect their economic interests ("designated officials").
- Assigns designated officials a disclosure category which requires them to disclose economic interests related to their job duties.
- Requires designated officials to file an annual Statement of Economic Interests (Form 700).

COI Code Revision Process

- Consolidation of disclosure categories to reflect the designated official's authority to make or influence decisions.
- Ensure consistent reporting among similar positions.
- Make Code easier to understand.

UC Obligations in Administering Sponsored Research

- UC assumes certain obligations by accepting sponsored projects
 - Compliance with state & federal regulations
 - Perform research or project with integrity
 - Stewardship of public assets
 - Upholding the public trust

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COI in Academic Research

- **Researchers** - A potential for COI exists if an individual:
 - Receives research support from, or evaluates therapies of a business in which he/she has an ownership interest (stock/options/deferred compensation)
 - Receives payments (consulting fees/honoraria-speaking fees/other) from an outside entity
 - Has a management position (Board of Directors, Chairman SAB, etc.)
 - Non-financial COI: Career advancement, personal advancement, scientific bias, glory...not easily identifiable or manageable

When is COI Disclosure Required for Sponsored Research?

Federal Research

- Disclosure form is required at the time of submission for any proposal being submitted to:
 - NIH (and other PHS agencies)
 - NSF
 - American Cancer Society (ACS)
 - American Heart Association (AHA)
 - California Institute for Regenerative Medicine (CIRM)
 - UC Managed Programs (Breast Cancer, Tobacco, etc.)
 - Subawards (applies to entities with funds originating from all agencies mentioned above)

Non-Federal Research

- A 700-U disclosure form is required when applying for or receiving funds for:
 - University Research Contracts & Grants
 - Research Gifts
 - Clinical Trial Agreements
 - UC-Discovery Grant Programs

Disclosure Requirements – Nongovernmental Sponsored Research

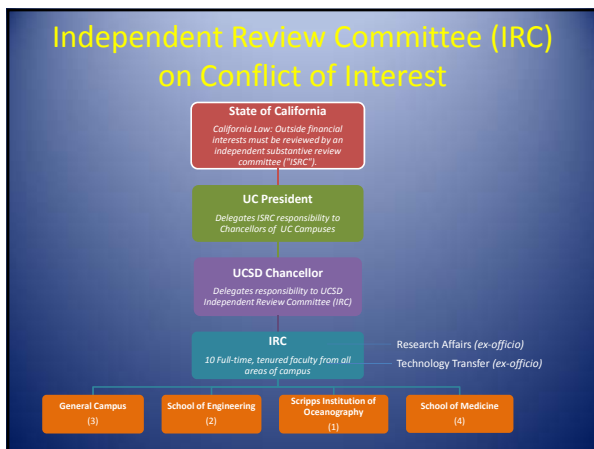
- When is disclosure required?
 - The 700-U form is required at the time of submission for contract and grant proposals being funded by a non-governmental entity
- Who must disclose
 - Principal Investigator
- What financial interests must be disclosed

A financial interest refers to the direct financial relationship between the principal investigator AND the non-governmental sponsor. Some examples of this include:

 - Management positions, Income, Investments, Personal gift(s), Receipt of loan(s), travel reimbursement from the sponsor
- How to disclose – Form 700-U

What Happens if an Investigator Discloses a Financial Interest?

- If a financial interest exists:
 - Investigator's financial disclosure forms must be reviewed and any conflict of interest must be managed by Independent Review Committee (IRC) on Conflict of Interest
 - The Conflict of Interest Office also informs the following parties that COI review must be completed before the project can move forward:
 - Investigator (and/or his staff, if appropriate)
 - Appropriate Sponsored Project Office (OCGA, OCTA, HSSPPO, etc.)
 - Appropriate Research Compliance Office (HRPP, IACUC, etc.)



Independent Review Committee of Conflict of Interest

- A faculty advisory committee appointed by the Chancellor to review the following items related to sponsored research :
 - The appearance a conflict of interest:
 - Determining the risk from the appearance of a conflict of interest regardless of whether an actual conflict exists or is managed
 - Risk for bias by the conflicted individual:
 - The extent to which the conflicted individual could compromise the integrity of the design, conduct or reporting of the research
 - Risk to the reputations of the conflicted individual and UCSD:
 - The extend to which the reputations of the conflicted researcher and UCSD could be damaged even if the conflict is managed
 - Risk to the human subjects participating in the research:
 - The extent to which the conflict of interest could increase or add risk to the human subject, depending on how the conflicted researcher recruits and treats subjects under the protocol

Case Study: Cameron Tucker

- Principal Investigator (PI): Dr. Cameron Tucker
 - The PI receives honoraria and travel reimbursement from Fizbo Pharmaceutical Corporation for speaking at events sponsored by the company.
 - In addition, he receives an annual consulting fee of \$25,000 for serving on the company's Scientific Advisory Board.
 - The company proposes to sponsor a Phase II clinical trial and the PI will evaluate the safety of the company's drug during the course of the study.



Case Study: IRC Management Plan

Dr. Tucker must discontinue recompensed activity during the course of the clinical trial.

No Income for Therapeutic/Diagnostic Studies

- Investigators who participate in a privately sponsored clinical trial may not receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study particularly when the proposed research involves therapeutic or diagnostic studies that alter patient care or test the company's products.

No income from companies supplying drugs, etc.

- Investigators are prohibited from consulting for a sponsor, the company supplying drugs and/or other materials to be used in the study, or any entity that may benefit from the results of the research.



Final Thoughts

- Research is an important and integral part of UC's mission.
- As stewards of public funds UC employees have an obligation to do the right thing.
- Know what resources are available to you.
- Reputation is everything!
 - It's easier to keep than to recover.
- Ask Questions!





Miscellaneous	University COI Code	Political Reform Act	Wild Card
200	200	200	200
400	400	400	400
600	600	600	600
800	800	800	800
1000	1000	1000	1000

Misc. : 200

- This Act requires public agencies to adopt a COI Code.
- **WHAT IS THE POLITICAL REFORM ACT?**

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Misc. : 400

- True or false: One of the goals of the Act is that public officials should perform their duties in an impartial manner, free from bias caused by their own financial interests or the financial interests of persons who have supported them.
- **WHAT IS TRUE?**

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Misc. : 600

- What is the name of the faculty advisory committee appointed by the Chancellor to review conflict of interest issues related to sponsored research?
- **WHAT IS THE INDEPENDENT REVIEW COMMITTEE?**

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Legislation: 1000

- Dr. Jones is a paid consultant for a device manufacturer that wants to sponsor a clinical trial to evaluate the device w/ Dr. Jones as the Principal Investigator. What must Dr. Jones do before the clinical trial can proceed at the University?
A. Disclose his financial interests and terminate his consulting activities with the manufacturer.
B. Continue to consult, but in a non-paid role.
C. Disclose his consulting on the informed consent.
- **WHAT IS #1?**

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Misc : 1000

- The Political Reform Act established this Commission, which (among other things) adopts regulations interpreting the Act.
- **WHAT IS THE FAIR POLITICAL PRACTICES COMMISSION OR THE FPPC?**

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University COI Code: 200

- True or False: The University COI Code identifies employees who make or influence decisions that could affect their economic interests.
- **True**

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University COI
Code: 400

- What form is required at the time of submission for contract and grant proposals being funded by a non-government agency.
- **WHAT IS A FORM 700U?**

Back

University COI
Code: 600

- Approximately how many University employees are required to file a Form 700 each year?
- **WHAT IS 1700**

Back

University COI
Code: 800

- True or False: The disclosure category for each designated official is determined by the first letter of their last name.
- **FALSE. Disclosure categories are assigned by the University based upon job duties.**

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University COI Code: 1000

- True or False: The code amendments planned for 2014 consolidate disclosure categories, harmonize positions, and make the Code easier to understand.
- **WHAT IS TRUE?**

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Political Reform Act: 200

- This group of University employees is subject to the disqualification rule of the Political Reform Act.
- **WHAT IS ALL UNIVERSITY EMPLOYEES?**

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Political Reform Act: 400

- True or false: Under the Political Reform Act, UC employees can't make UC decisions that will affect their economic interests, but it's always okay for them to make recommendations about those decisions – so long as they don't make the actual decision.
- **WHAT IS FALSE?**

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Political Reform Act: 600

- True or false: Under the Political Reform Act, a spouse or registered domestic partner's economic interests are never counted as an employee's economic interests.
- **WHAT IS FALSE?**

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Political Reform Act: 800

- True or false: The Regents are not University employees, so they are not subject to the disqualification rule of the Political Reform Act.
- **WHAT IS FALSE?**

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Political Reform Act: 1000

- The FPPC has the authority to impose this kind of penalty for violations of the Political Reform Act.
- **WHAT IS A FINE?**

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Wild Card: 200

- Violations of the various COI laws and requirements can lead to:
 - (a) Fines and penalties
 - (b) Suspension
 - (c) Termination
 - (d) All of the Above
- **WHAT IS (d) ALL OF THE ABOVE?**

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Wild Card: 400

- What is the "Rule" that requires UC employees to remove themselves from participating in University decisions in which they have a conflict of interest?
- **WHAT IS THE DISQUALIFICATION RULE?**

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Wild Card : 600

- Resources for your COI questions include:
 - (a) Campus and UCOP COI Coordinators
 - (b) UCOP Ethics Training
 - (c) UCOP COI resource webpage
 - (d) All of the Above
- **WHAT IS (d) ALL OF THE ABOVE?**

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Wild Card: 800

- You are offered free plane tickets and waived registration fees to attend a conference to give a presentation on a project you manage. Do you:
 - (a) Accept the tickets and attend the conference.
 - (b) Notify your supervisor.
 - (c) Possibly consult with the campus COI Coordinator.
 - (d) Both b and c
- BOTH (b) and (c)**

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Wild Card: 1000

- Your department is discussing a public/private partnership, and you are tasked with leading the team. Should you:
 - (a) Involve Campus Counsel and OGC as soon as possible.
 - (b) Employ a dart-throwing monkey to make key decisions.
 - (c) Create the new entity, giving yourself a new position with a big raise.
- THE ANSWER IS A**

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