University/Industry Relationships and Conflict of Interest

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Agenda

- Conflict of Interest
- University/Industry Relationships
- Disclosure Requirements
- Conflict of Interest Oversight Committee
- Conflict of Interest and Graduate Education
- Resources
Conflict of Interest

A situation where an investigator's outside financial interests (e.g., salaries; consulting income; equity interests; honoraria; gifts; loans; or travel payments) or paid or unpaid obligations (e.g., director, officer, partner, consultant or manager of an entity) bias or have the potential to bias a research project.
What is a Financial Interest?

Anything of economic value from an outside entity including:

- **Equity** - stock, stock options
- **Income** - salary, consulting fees, honorarium, stipend
- Travel payments/reimbursements
- Loans
UC and UC Irvine

Financial Interests
- Intellectual property
- Resources
  - employees
  - land
  - buildings
  - brand

Research Mission
- Unbiased research
- Open research
- Patient safety/privacy

Educational Mission
- Pedagogy

UC Employees
Financial Interests
- Stock
- Income
- Gifts
- Patents
- Royalties

Industry
Financial Interests
- Product value
- Marketability
- Patents (Capitalization)
Public Perception

- The University of California wants to protect its brand, image, and reputation.
- You are required to disclose your financial interests and potential conflicts to the University.
- Public perception is important when considering a conflict of interest.
Examples

- The researcher has a financial interest in an entity that might manufacture and commercialize a drug used in the research project.
- The researcher has created a company that licensed the UC intellectual property being tested in a UCI research project.
University/Industry Relationships
The **Bayh-Dole Act** or **University and Small Business Patent Procedures Act of 1980** gave US universities, small businesses, and non-profits rights to intellectual property resulting from federal funding. Prior to that, the U.S. government retained the patent rights and would not grant exclusive licenses.
Key Points

- The University of California wants you to patent (licensable) inventions and promises you royalties.
- Licensable scientific inventions can lead to a substantial financial interest.
- If you (a UC employee) receive income that is not from or through UC, then the University wants to know if it has the potential to conflict with the interests of the University.
UC Patent Policy

UC employees, persons who use UC research facilities, and persons who receive gift, grant or contract funds through the university are all required to sign the University Patent Acknowledgment, which requires you to:

• Disclose to the UC all your inventions
• Assign inventions and patents to the University
Show Me the Money

- UC does not make money by manufacturing and selling products. It makes money by licensing patents to companies that make and sell products.

- UCI Royalty Sharing Agreement:
  - 50% The University of California
  - 15% The Department
  - 35% The Inventors (you)
UCI Office of Technology Licensing

- 126 invention disclosures
- 964 active inventions
- 445 active U.S. patents
- 7 startup companies formed
- $12,124 total royalty and fee income

UCI is still waiting for the big one.
A Win-Win-Win Situation:

- Northwestern University professor synthesizes pregabalin in 1989 and showed activity against epilepsy. Northwestern sold the patent to Pfizer.
- FDA approved Lyrica in 2004 and by 2012 annual sales had reached $4.2 billion.
- Northwestern University royalties > $700 Million.
- Professor royalties? (He endowed a $95 million research center at Northwestern).
- Pfizer, employees, and Professor Silverman pay taxes.
A Win-Lose Situation:

- Craig Thompson, Director of the Abramson Family Cancer Research Institute at the University of Pennsylvania founded Agios Pharmaceuticals.
- Thompson was sued for $1 billion by both the Institute and the University claiming that the company was founded on technology they owned.

University Sues Researcher” Reported January 3, 2012
http://the-scientist.com/2012/01/03/university-sues-researcher/
Felony Charges for Failure to Disclose Financial Interests

- UCI professor of more than 25 years, pleaded guilty to failing to disclose his secret payments ($300K-$700K) from foreign companies funding his academic research.
- He owes more than $400,000 in restitution and costs to the university, and was sentenced to 3 years probation.
- He is the first UC professor criminally charged and convicted for violating the state’s system for monitoring/preventing conflicts of interest on the 10 UC campuses.
Greater Scrutiny

Physician Payment Sunshine Act - 2013

- US manufacturers of drugs, devices, and medical supplies covered under Medicare, Medicaid, or SCHIP must report payments to physicians and teaching hospitals annually to Department of Health and Human Services, which will post information on public website.

- Must also disclose physician ownership or investment interest.

- Law exempts payments less than $10 until the aggregate annual total per company, per covered recipient, reaches $100, then all retroactive payments must be disclosed.

COI Disclosure Policies

State of California
Federal Government (NSF, PHS)
Human Subjects (IRB)
State

- Required for non-governmental sponsored research and research gifts (i.e. private companies and nonprofit organizations)
- Principal investigators are required to disclose financial interests in the non-governmental sponsor
State Disclosure Thresholds

- If you, the Principal Investigator, have received one or more of the following from the nongovernmental sponsor of your research:
  - Income ≥ $500
  - Equity ≥ $2,000
  - Personal gifts ≥ $50
  - Travel payment
  - Ownership or management interests/position; consulting/employment relationship
  - Loan

  ... then you would be required to submit a COI Addendum for review
Federal (NSF)

- Required for NSF research contract/grant including subaward where NSF is the prime sponsor and funding from organizations following these federal disclosure requirements
- **All persons** involved in design, conduct, or reporting of research being funded by NSF are required to disclose their significant and related financial interests
NSF Disclosure Thresholds

If you are responsible for design, conduct or reporting of the NSF funded research and received one or more of the following from an outside entity with interests related to the research:

- Income ≥ $10,000
- Equity ≥ $10,000 or 5%
- Intellectual Property not owned by UC

...submit a COI Addendum for review if financial interest is related to research
PHS - Revised in 2011

- Required for PHS research contract/grant including subaward where PHS is the prime sponsor and funding from organizations following these federal disclosure requirements

- All persons involved in design, conduct, or reporting of research being funded by PHS are required to disclose their significant financial interests related to their institutional responsibilities
If you are responsible for design, conduct or reporting of the PHS funded research and received one or more of the following from an outside entity with interests related to your institutional responsibilities:

- Public Companies: total compensation and equity interest >$5,000
- Private Companies: income >$5,000 or any equity interest (equity in private companies is hard to value)
- Outside patent income (not UC) >$5,000
- Travel related to the institutional responsibilities

...then you would indicate “Yes” on your Annual Disclosure in Kuali Coeus except for travel.
Why Doesn't the Federal Government Trust Us?

- Feb 4, 2015 - Yujie Ding and Yuliya Zotova were charged with ten counts of wire fraud related to mis-use of a Small Business Innovation Research (SBIR) grant from NASA.
- Their proposal claimed they would carry out research at their company ArkLight, and subcontract work to their university labs. Arklight never existed. They funneled the money to themselves and their university research.
- If convicted, maximum sentence is 200 years in prison and a fine of up to $2.5 million.

Human Subjects (IRB)

- Required for any study involving human subjects
- All individuals listed in the protocol application as research personnel must disclose their financial interests related to the research
IRB Disclosure Thresholds

If you are listed as Research Personnel on the protocol application and received one or more of the following from an outside entity with interests related to the research:
- Income $\geq 10,000$
- Equity $\geq 10,000$ or 5% in a publicly traded entity
- Any equity in a privately held company
- Director, Officer, Employee, Partner, Trustee, Consultant, or Management position
- Outside Patents (not owned by UC)

...then you would indicate “Yes” on the IRB application and submit a COI Addendum for review.
Conflict of Interest
Oversight Committee
Conflict of Interest Oversight Committee (COIOC)

- **COIOC**: Faculty members from various schools
- **Ex officio members**
  - Bruce Morgan – Associate Vice Chancellor of Research Administration
  - Nadia Wong – COI Administrator
  - Amy Green – COI Analyst
  - Kevin Kennan – Associate Director, Intellectual Property Administration (Applied Innovation)
  - Marianne Liu Beckett - Director, Academic Employee Relations and Faculty Development (Academic Personnel Office)
  - Sheila Morris – Executive Director, Academic Affairs and Faculty Compensation

- Finally, COIOC makes a recommendation to the Vice Chancellor of Research for:
  - (1) approval
  - (2) management
  - (3) disapproval
COIOC

- Not a punitive body
- We want the money to keep flowing
- We expect you to be transparent
- We will work with you to protect the interests of the University
COIOC Procedures

- Investigator/Researcher discloses financial interests. **YOUR RESPONSIBILITY**
- COIOC reviews disclosure
  - We review WHAT YOU DISCLOSE
  - We are not responsible for DISCOVERING your conflict
- Determines whether or not conflict is manageable
- Send recommendation to Institutional Official
- Implement management plan
COI Management Strategies

- Public disclosure in publications and presentations
- Monitoring by independent reviewers
- Disqualification from project participation
- Divestiture
- Severance of relationships that create COI
- Notification of sponsor (NIH, NSF, others)
Example of a proper COI disclosure in a publication.

Up-regulating BDNF with an ampakine rescues synaptic plasticity and memory in Huntington’s disease knockin mice

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V.F. performed research; L.P. contributed new reagents/analytic tools; D.A.S., C.S.R., and G.L. analyzed data; and D.A.S., C.S.R., C.M.G., and G.L. wrote the paper.

Conflict of interest statement: G.L. is a consultant for and has financial interests in Cortex Pharmaceuticals, Inc., which provided the ampakine used in this study.

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COI & Graduate Students
How does COI relate to graduate education?

Scenario 1: Your P.I. owns stock in a company that stands to benefit from your research. The faculty member directs you to delay publication of your dissertation and graduation to maintain the value of the P.I.'s shares.

Scenario 2: A faculty member starts a company related to a student's research. The company is supporting the Faculty member’s research in that area. The faculty member pressures a student to divert work from their thesis project to do research that will benefit the company.
When is the best time to raise a concern about a COI?

When thesis advisor and project are chosen or anytime student has a concern. School has a form that must be signed at the end of the first year when student transfers from the Gateway Program to a lab.

Who can identify and report a conflict of interest?

The student, advisor, dept. chair or grad. advisor, assoc. dean or director of grad program, the campus COI OC.
What are the responsibilities of my academic unit?

- Notify students of the nature of COI and UC policy.
- Provide students with name of Designated Resource Person – typically the dept. grad advisor.
- Ensure faculty are informed about COI policy and procedures (APM-028), and how these might affect their relationship with students.
What is the responsibility of the thesis advisor?

Disclose any pertinent COIs to students and the Dept. Grad. advisor in a timely manner.

Is there COI-related documentation that I should be aware of?

• Departmental Transfer Agreement: end of 1st year.
• Advancement to Candidacy.
# Management of COIs in Graduate Education

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<th>1st Year - Gateway Program</th>
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<td><strong>2nd Year - Transfer Agreement</strong></td>
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<td>If COI, appoint Oversight Member to Thesis Committee</td>
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**Advancement to Candidacy**
If COI, Oversight Member on Advancement Committee

**Thesis Defense**
If COI, Oversight Member on Thesis Committee
Managing a COI Involving a Graduate Student

1. Process initiated by student, faculty mentor, Chair, or COIOC
2. Report potential COI Designated Resource Person (usually departmental Graduate Advisor) or Department Chair
3. If DRP determines COI issue may be harmful to student, DRP notifies Dean of Graduate Studies requesting an Oversight Member be appointed
4. Dean of Graduate Studies selects an Oversight Member from a list of 3 nominations agreed upon by the student, faculty research advisor, and DRP
Oversight Member

- Participates as a non-voting Ex Officio Member in all student research advisory and/or thesis/dissertation committee meetings.
- Is aware of COI issues and relevant campus policies
Oversight Member

- Determine whether any harmful results from COI issues
  
  - If no harmful results from COI issues, sign brief statement to that effect after each committee meeting and sign advancement to candidacy and final exam forms.
  
  - If problem arising from COI issues, does not sign advancement to candidacy or final exam forms and does inform Dean of Graduate Studies of problem.

- Dean of Graduate Studies responsible for determining solution.
Resources
COI Resources

- COI in Graduate Education FAQs

- Conflict of Interest Office
  - Nadia Wong, COI Administrator [nadiaw@uci.edu](mailto:nadiaw@uci.edu)
  - Amy Green, COI Analyst [acgreen1@uci.edu](mailto:acgreen1@uci.edu)
Resources for non-COI Concerns...

- **Whistleblower Policy**

  If suspect improper governmental activities (such as corruption, bribery, theft or misuse of university property, fraudulent claims, fraud, coercion, willful omission to perform duty; or economic waste; or gross misconduct, gross incompetence or gross inefficiency; or any condition that may significantly threaten the health or safety of employees or the public). The report can be submitted anonymously by calling 800-403-4744 or submitting a report online at [http://universityofcalifornia.edu/hotline](http://universityofcalifornia.edu/hotline).
Resources for non-COI Concerns

- **Research Misconduct**
  

  Research Misconduct is defined by federal law and University policy as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Office of the Ombudsman**
  

  The Office of the Ombudsman provides a safe and comfortable environment to discuss complaints, concerns or problems confidentially. The office is confidential, informal, and neutral. To make an in person or telephone appointment, or if you have any questions, please contact the office at (949) 824-7256 or (714) 456-5605.