

Conflict of Interest Updates

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COI Services

Goal: To help researchers navigate COI policies and COIOC review

- Collect and process financial disclosures
- Conduct staff pre-reviews to address potential COIOC concerns to avoid the disclosure being tabled
 - May email faculty for additional information
- Advise faculty on COI issues related to financial interests and start-up companies

COI Disclosure Chart

- 3 different COI policies based on research sponsor
- 1 COI policy for human subjects research
- Disclosure Chart: <http://www.research.uci.edu/compliance/conflict-of-interest/index.html>

UC Irvine Conflict of Interest Disclosure Chart			
*Non-UCI Investigators/Researchers have different COI forms. Refer to http://www.research.uci.edu/compliance/conflict-of-interest/forms-references/index.html			
STATE LAW	FEDERAL POLICY (NSF FUNDING)	FEDERAL REGULATIONS (PHS FUNDING)	HUMAN SUBJECTS (DHHS Guidelines 2004)
Reporting Triggers			
<ul style="list-style-type: none"> • Research contract/grant from a non-governmental entity • Research Gifts earmarked for a specific individual or a specific research project • Material Transfer Agreement <p><i>Note: Exclude all exempt sponsors on FPPC approved list and all non-profit, tax-exempt educational institutions. However, researchers must disclose for the prime sponsor if the educational institution received its funds from a non-governmental entity.</i></p>	<ul style="list-style-type: none"> • NSF research contract/grant • Non-governmental entity which flows down NSF funds • UC Discovery Grant • California Institute for Regenerative Medicine (CIRM) Grant • UC Special Research Programs (HIV/AIDS, breast cancer and tobacco related disease) <p><i>Note: Exclude Phase 1 SBIR or STTR grants</i></p>	<ul style="list-style-type: none"> • PHS research contract/grant • Non-governmental entity which flows down PHS funds • Research Funding from organizations that follow PHS disclosure requirements (i.e., American Cancer Society, American Heart Association). Complete list at: http://www.research.uci.edu/compliance/conflict-of-interest/research-disclosures/awcencs-orgs-phs.html <p><i>Note: Exclude Phase 1 SBIR or STTR grants</i></p>	Any study involving human subjects
Who Must Disclose			
UCI Principal Investigator and co-Principal Investigator, if applicable	UCI Investigator(s) (individuals responsible for the design, conduct, or reporting of the funded research project)	UCI Investigator(s) (individuals responsible for the design, conduct, or reporting of the funded research project)	All individuals listed in the protocol application as research personnel
What to Disclose			
<p>A financial interest in the non-governmental sponsor of the research including:</p> <ul style="list-style-type: none"> • Income ≥ \$500 • Investments ≥ \$2,000 • Director, Officer, Employee, Partner, Trustee, Consultant or Management position • Loan Balances ≥ \$500 • Personal Gifts Valued at ≥ \$50 • Travel Reimbursements <p><i>Note: Financial interests received within 12 months prior to submission must be reported for the disclosing individual and his/her spouse or registered domestic partner, and dependent children.</i></p>	<p>A significant financial interest related to the research project including:</p> <ul style="list-style-type: none"> • Income ≥ \$10,000 • Equity (of any type) > \$10,000 or 5% • Director, Officer, Employee, Partner, Trustee, Consultant or Management position • Intellectual Property (excluding intellectual property owned by the UC.) <p><i>Note: Financial interests received within 12 months prior to submission must be reported for the disclosing individual and his/her spouse or registered domestic partner, and dependent children.</i></p>	<p>A significant financial interest related to the investigator's institutional responsibilities including:</p> <ul style="list-style-type: none"> • If publicly traded entity, total value of compensation and equity interest > \$5,000 • If non-publicly traded entity, total value of compensation > \$5,000 or any equity interest • Income received related to intellectual property > \$5,000 (excluding intellectual property owned by the UC.) • Any reimbursed or sponsored travel (excluding [1] travel that is reimbursed or sponsored by a Federal, state, local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education; or [2] sponsored or reimbursed travel for the Investigator's spouse/registered domestic partner and/or dependent children.) <p><i>Note: Financial interests received within 12 months prior to submission must be reported for the disclosing individual and his/her spouse or registered domestic partner, and dependent children.</i></p>	<p>A discloseable financial interest related to the research including:</p> <ul style="list-style-type: none"> • Income ≥ \$10,000 • Equity ≥ \$10,000 or 5% in a publicly traded company • Equity in a privately held company, regardless of the value • Director, Officer, Employee, Partner, Trustee, Consultant or Management position • Intellectual Property (excluding intellectual property owned by the UC.) <p><i>Note: Financial interests received within 12 months prior to submission must be reported for the disclosing individual and his/her spouse or registered domestic partner, and dependent children.</i></p>
When to Disclose			
<ul style="list-style-type: none"> • With the initial proposal • With additional funding <p><i>Note: All positive disclosures must be reviewed and approved prior to acceptance of the award or additional funding.</i></p>	<ul style="list-style-type: none"> • With the initial proposal • When new personnel are added • With any change in an investigator's financial interest <p><i>Note: All positive disclosures must be reviewed and approved prior to acceptance of the award or additional funding.</i></p>	<ul style="list-style-type: none"> • With the initial and renewal proposals • With supplemental funding proposal • With non-competing continuation • With no cost time extension • When new personnel are added • With any new significant financial interest (New significant financial interests must be reported within 30 days of acquiring or discovering the new SPI for the disclosing individual and his/her spouse/registered domestic partner and dependent children.) <p><i>Note: Disclosures are required at least annually for duration of award. All positive disclosures must be reviewed and approved prior to expenditure of funds.</i></p>	<ul style="list-style-type: none"> • With the initial protocol • With any continuing IRB application • With any modification request that changes the Lead Researcher or adds Co-Researchers or other research personnel <p><i>Note: All positive disclosures must be reviewed and approved prior to IRB review and approval of the protocol.</i></p>
Disclosure Forms to Submit			
<ul style="list-style-type: none"> • State Disclosure (Form 700-1) • Addendum for All Positive Disclosures (Form COI-1) or Gift Addendum (Form COI-2), if necessary 	<ul style="list-style-type: none"> • NSF Disclosure (Form 900) • Addendum for All Positive Disclosures (Form COI-1), if necessary 	<ul style="list-style-type: none"> • PHS Disclosure (Form 800) • Addendum (Form 810), if necessary • PHS Addendum (Form 830), if necessary 	<ul style="list-style-type: none"> • Application for IRB Review • PHS Appendix (Form 810), if necessary • Positive Disclosures (Form COI-1), if necessary

COI Disclosure Form Reference

- Identify which sponsor-related disclosure requirements apply

- Disclosure Form Reference: <http://www.research.uci.edu/compliance/conflict-of-interest/index.html>

Disclosure Form Reference		
Direct Sponsor: Award to UCI		
<ul style="list-style-type: none"> • When UCI is receiving funds directly from the sponsor (UCI is not a subrecipient), evaluate UCI's direct sponsor to determine the disclosure requirements. 		
Prime Sponsor: Subrecipient Award to UCI		
<ul style="list-style-type: none"> • In cases where UCI is a subrecipient, evaluate <u>both</u> UCI's direct sponsor and the prime sponsor to determine the disclosure requirements. • Example: Subcontract from University A with Organization following PHS Regulations as prime sponsor Based on Direct Sponsor (University A), no Form 700U required since non-profit, tax exempt educational institution. Based on Prime Sponsor (Organization following PHS regulations), collect Form 800 from all Investigators. 		
If Direct Sponsor is...	Public Health Service (PHS)	All Investigators submit Form 800
	Organizations following PHS regulations	All Investigators submit Form 800
	National Science Foundation (NSF)	All Investigators submit Form 900
	CIRM/UC Special Research Programs	All Investigators submit Form 900
	Non-governmental entity (including non-profit foundations)	Principal Investigator & Co-Principal Investigator (if applicable) submit Form 700U
	Contract Research Organization (only if CRO signed agreement with UCI)	Principal Investigator & Co-Principal Investigator (if applicable) each submit a Form 700U for CRO and a Form 700U for drug or device manufacturer of study
	Non-governmental entity on exempt list for state disclosure requirement	No Form 700U required
	Non-profit, tax exempt educational institution	No Form 700U required
	Foreign governmental entity	No disclosure requirements
Governmental entity not PHS or NSF	No disclosure requirements	
If Prime Sponsor is... (applicable when UCI is subrecipient)	Public Health Service SBIR/STTR Phase I	No Form 800 required
	Public Health Service (including SBIR/STTR Phase II)	All Investigators submit Form 800
	Organizations following PHS regulations	All Investigators submit Form 800
	National Science Foundation SBIR/STTR Phase I	No Form 900 required
	National Science Foundation (including SBIR/STTR Phase II)	All Investigators submit Form 900
	CIRM/UC Special Research Programs	All Investigators submit Form 900
	Non-governmental entity (including non-profit foundations)	Principal Investigator & Co-Principal Investigator (if applicable) submit Form 700U
	Non-governmental entity on exempt list for state disclosure requirement	No 700U required
	Foreign governmental entity	No disclosure requirements
Governmental entity not PHS or NSF	No disclosure requirements	
<p>Notes: "Investigator" is defined as an individual responsible for the design, conduct, or reporting of the funded research project. Non-UCI Investigator(s) may have different disclosure forms—refer to Conflict of Interest Forms webpage below.</p> <p>Other Examples:</p> <ul style="list-style-type: none"> • NSF STTR Phase II Subcontract from Entity A (non-profit foundation not on exempt list) Based on Direct Sponsor (Entity A), collect Form 700U from Principal Investigator & Co-Principal Investigator (if applicable). Based on Prime Sponsor (NSF STTR Phase II), collect Form 900 from all Investigators. • NIH SBIR Phase I subcontract from Company X (for-profit) Based on Direct Sponsor (Company X), collect Form 700U from Principal Investigator & Co-Principal Investigator (if applicable). Based on Prime Sponsor (NIH- PHS Agency), no Form 800 required since SBIR Phase I. • Company C (for-profit) subcontract with Company D (for-profit) as prime sponsor Based on Direct Sponsor (Company C), collect Form 700U from Principal Investigator & Co-Principal Investigator (if applicable). Based on Prime Sponsor (Company D), collect Form 700U from Principal Investigator & Co-Principal Investigator (if applicable). <p>Forms available at: http://www.research.uci.edu/compliance/conflict-of-interest/forms-references/index.html</p> <p>University of California, Irvine Conflict of Interest</p>		

COI Case Studies

The screenshot shows the UCI Research Office website. The header includes the UCI Irvine logo and the text 'OFFICE OF RESEARCH'. A navigation menu lists various categories: About Office of Research, Sponsored Projects, Regulatory Compliance, Research Development, Integrity in Research, UCI Technology Alliances, Centers & Institutes, Facilities & Services, Training & Education, and Policy Library. The left sidebar is titled 'Regulatory Compliance' and lists several sub-sections, with 'Conflict of Interest' selected. The main content area is titled 'COI Case Studies' and includes a 'Printable Version' link. The text explains that researchers must disclose their outside financial interests to UCI. It provides two case studies: Case 1, where a PI has equity in a company sponsoring their project, and Case 2, where a professor is a co-founder and scientific advisor to a company. A bulleted list of safeguards for Case 1 is also provided.

UCI IRVINE OFFICE OF RESEARCH

Researcher's Toolbox Contact Us | Applications & Forms

Regulatory Compliance

Conflict of Interest

COI Case Studies

Printable Version

To comply with federal regulations and state laws, all researchers are required to disclose to UCI their outside financial interests related to their research projects. In addition, researchers are also required to disclose their financial interests in publications and presentations related to those research projects to promote transparency, and disclose all inventions arising from those research projects to UCI's Office of Technology Alliances.

The strategies and methods below are examples of safeguards that the Conflict of Interest Oversight Committee (COIOC) may require to address the potential risks of a conflict of interest, in addition to UCI's standard publication/presentation and intellectual property disclosure requirements. Please note that each situation is unique and the following safeguards do not guarantee the COIOC's approval.

For researchers with financial interests that are related to their research projects, please consider adding appropriate safeguards as you design your study to proactively address the potential risks of a conflict of interest. To facilitate the COIOC's review, please highlight the safeguards you have implemented to ensure the objectivity of the research in light of the related financial interests in your Conflict of Interest Addendum.

Financial Interest Case 1: A Principal Investigator (PI) has equity interests in and received income from Company A, which is sponsoring her research project involving their product.

Safeguards to address potential risks of a conflict of interest:

- The PI established a standard operating procedure that blinds the study, which includes:
 - Non-conflicted Researcher B codes the different compounds to be used in the study.
 - Non-conflicted Researcher C conducts the experiments on the different compounds, including data analysis and graphing. The PI is not involved in the blinding or data collection.
 - The results are presented to the PI, after which the non-conflicted Researcher B reveals the code for the experiment.
- Inventions arising from the related research are reported to UCI's Office of Technology Alliances. The PI will not participate in any decision making process regarding the licensing of the inventions.

Financial Interest Case 2: Professor D is a co-founder of Company E, serves as a scientific advisor and holds equity interests in Company E. Professor D will be PI on subcontract from entity.

- Examples of how others have addressed COIOC's concerns

- COI Case Studies:
<http://www.research.uci.edu/compliance/conflict-of-interest/coi/case-studies.html>

Updates

SPA Listserv

- PHS T32 Training Grants- collect Form 800 only from PI/Director and Co-Director (if applicable)
- Contract Research Organizations & 700Us
 - Who signed the research agreement with UCI?
 - CRO- need 700Us for CRO *and* drug/device manufacturer
 - Not CRO- need 700U only for drug/device manufacturer

Tips

- To avoid a delay, encourage faculty to respond to COI emails
- Refer faculty to COI Staff if they are considering starting a company or acquiring a new financial interest
- Contact COI Staff if you have any COI related questions or suggestions

THANK YOU! Questions?

<http://www.research.uci.edu/compliance/conflict-of-interest/index.html>

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