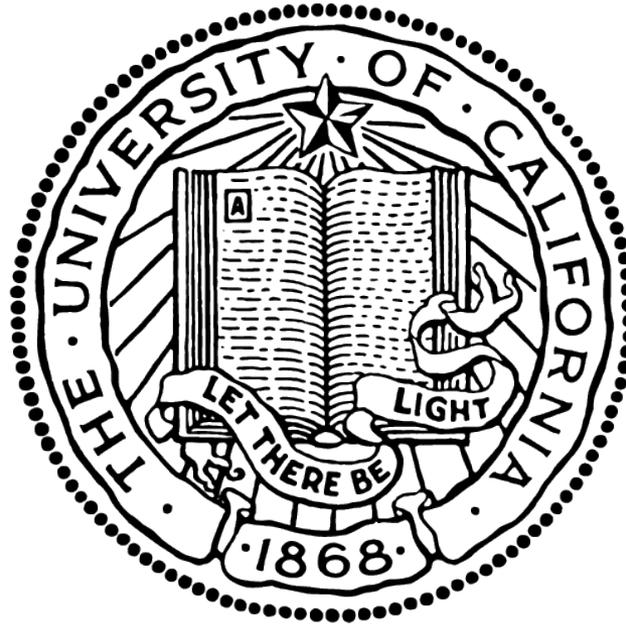


# UC Conflict of Interest Training for Public Health Service Investigators (COI-PHS)



## University of California

# UC Conflict of Interest Training for Public Health Service Investigators (COI-PHS)

This material is a copy of the online training version of this  
module.

This material is provided for information purposes only and  
cannot be used for completion of the course requirement

# Training Objectives

By the end of this training, you will have learned :

- What you need to disclose under the new Public Health Service (PHS) regulations
- When you need to disclose to the University
- What the University does with these disclosures
- How the new regulations are applied in a few case examples

The content of this training is intended for all PHS-funded researchers of the University who are considered Investigators under the PHS regulations, and should take approximately 15-20 minutes to complete.

For specific information about implementation of the PHS conflict of interest regulations on your campus, please visit the following links:

[UC Campus Conflict of Interest Programs](#)  
[UC Campus Academic Conflict of Interest Coordinators](#)

# New -- Public Health Service Conflict of Interest Regulations

## What am I required to disclose?

The Public Health Service (PHS) initially issued conflict of interest regulations in 1995. They were recently revised in some important ways. The revised PHS regulations go into effect on August 24, 2012. Under these regulations, **Investigators are expected to disclose all Significant Financial Interests.**

Under the new regulations, as implemented by the University, the following definitions apply:

- **Investigator** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- **Institutional Responsibilities** means teaching/education, research, outreach, clinical service, and University and public service performed on behalf of the University of California which are within the course and scope of the Investigator's University of California employment/appointment.

All PHS Investigators should review the UC Policy: *Disclosure of Financial Interests & Management of Conflicts of Interest Re: Public Health Service Research Awards*

on the [UC Research Integrity/Conflicts of Interest and Sponsored Research](#) web page.

# New -- Public Health Service Conflict of Interest Regulations

## What am I required to disclose? (cont'd)

**Significant Financial Interest** under the new PHS rules means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or registered domestic partner and dependent children, unless noted otherwise below) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

### 1. For a publicly traded entity

The value of any remuneration received from the entity in the twelve months preceding the disclosure which when added to the value of any equity interest in the entity as of the date of disclosure, exceeds \$5,000.

### 2. For a non-publicly traded entity

Remuneration received from the entity during the twelve months preceding the disclosure that exceeds \$5,000, or when the Investigator holds **any** equity interest in the entity.

- **Remuneration** includes salary (other than salary provided by the University of California) and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship).
- **Equity interest** includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

# New -- Public Health Service Conflict of Interest Regulations

## What am I required to disclose? (cont'd)

### 3. Intellectual Property Rights

Any income from intellectual property (i.e. copyrights or patents) that is **not owned** by the Regents of the University of California that exceeds \$5,000 during the previous twelve months.

### 4. Travel

Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities except for travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education (for the Investigator only).

**Example:** Travel reimbursement to attend an American Heart Association grant review panel or to a clinical trial investigator's meeting must be disclosed.

# PHS Conflict of Interest Regulations - Disclosure Timelines

## When do I need to disclose Significant Financial Interests?

PHS Investigators are required to disclose to their campus **all Significant Financial Interests** no later than at the time of the application for PHS funding.

Additionally, Investigators have an ongoing duty throughout the period of the award to disclose their (and those of their spouses or registered domestic partners, and dependent children) Significant Financial Interests according to the following timelines:

- **Within thirty days** of discovering or acquiring any new Significant Financial Interest; and
- **At least annually** throughout the period of the award.

Please note: this annual disclosure is a new requirement imposed by PHS; the University is trying to develop systems and guidance to make it as simple as possible for Investigators and the University to fulfill their responsibilities.

- **Before joining an on-going PHS-funded research project**, new Investigators must also complete a disclosure of Significant Financial Interests.

# PHS Conflict of Interest Regulations - Disclosure Management

## How will the University manage my disclosure?

Following receipt of the disclosure of all Significant Financial Interests, a designated official or campus COI Review Committee shall:

1. Review the disclosure of the Significant Financial Interest(s).
2. Determine whether any Significant Financial Interests are related to PHS-funded research.
3. Determine whether a financial conflict of interest exists (i.e., whether the SFI could directly and significantly affect the design, conduct or reporting of the PHS-funded research).
4. If a conflict exists, develop and implement a plan that shall specify the actions that have been, and shall be, taken either to eliminate or manage such financial conflict(s) of interest.

# PHS Conflict of Interest Regulations – Reporting

## **How are financial conflicts of interest reported to the funding agency?**

Prior to the University's expenditure of any funds provided under a PHS award, the University must provide a report about the Investigator's financial conflicts of interest to the PHS funding agency. The report must include information about the way in which the financial conflicts of interest will be managed. It must also include confirmation of the Investigator's agreement to abide by the conditions of the management plan and a description of the way in which the plan will be monitored.

It is important to note that if financial conflicts of interest are eliminated before research funds are expended, the University is not required to submit such a report to the PHS funding agency.

# PHS Conflict of Interest Regulations – Training Requirements

Each Investigator is required to complete PHS conflict of interest training prior to engaging in PHS-supported research at the University of California, and at least every four years, and immediately when any of the following circumstances apply:

1. A campus finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
2. The campus revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators.

# PHS Conflict of Interest Regulations – Additional Information

## Public Access

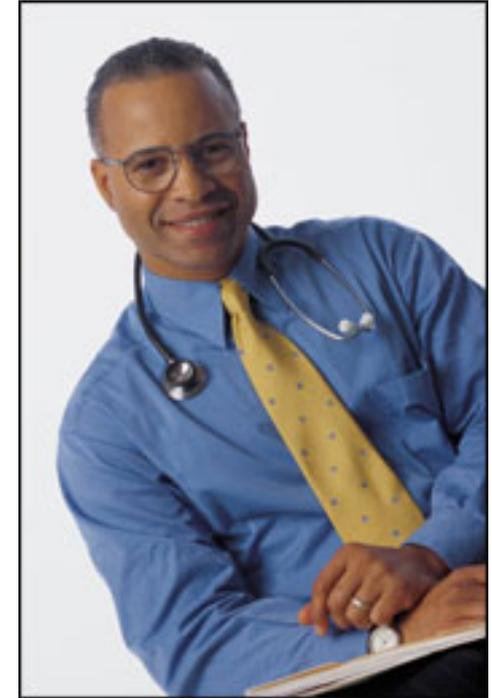
Under the University's implementation of the PHS policy, campuses must provide a written response to any requestor (the public), within five business days of a request for information concerning any Significant Financial Interest disclosed to the Institution by (and still held by) the Principal Investigator and other Key Personnel on a PHS-supported project that was determined by the institution to relate to the PHS-funded research and to constitute a financial conflict of interest.

## Sanctions

Failure to file a complete disclosure of financial interest, required updates, or failure to comply with any conditions or restrictions directed or imposed on the conduct of the project under *Disclosure of Financial Interests & Management of Conflicts of Interest Re: Public Health Service Research Awards* will be grounds for discipline pursuant to the University Policy on Faculty Conduct and the Administration of Discipline (Academic Personnel Manual, [APM-016](#)) and/or other applicable employee or student disciplinary policies.

# Scenario: An Affair of the Heart

Dr. De la Coeur is faculty member who is both a practicing cardiologist and conducts research on heart disease. He wishes to serve as principal investigator on an NIH grant that supports a cutting-edge therapy program for heart disease patients at one of the University's medical centers. Dr. De la Coeur owns 4% of Heart Therapy Inc. (HTI), a privately held company. Should the therapy prove to be successful, HTI could become very profitable to the investors and the University from which it has licensed intellectual property.



**Does Dr. De la Coeur's ownership interest in HTI have to be disclosed?**

- A. Yes
- B. No

Feedback Text

The best answer is A. Click the Next button to read a discussion of this scenario.

# Discussion: An Affair of the Heart

In this scenario, HTI is a non-publically traded entity and, under the new regulations, disclosure is required when an investigator holds any equity in such an entity and the financial interest (equity) is reasonably related to the Investigator's Institutional Responsibilities. Dr. De la Coeur conducts research, teaches, and has patient care responsibilities that are based on his expertise and credentials as a cardiologist for the University of California. Thus, his financial interest in HTI is related to his Institutional Responsibilities. He therefore must disclose his Significant Financial Interest in HTI to the University.

The University must then determine whether this Significant Financial Interest (and any others that he has disclosed) is related to his NIH-funded research project, and if so, whether it constitutes a financial conflict of interest. To do that, a reviewer must reasonably determine that this Significant Financial Interest could “directly and significantly affect the design, conduct of reporting of...” the NIH-funded project. If Dr. De la Coeur's equity in HTI is considered to be a financial conflict of interest, it must be eliminated, reduced, or managed. In addition, most journals would likely require disclosure of the ownership interest in publications as would most University COI Review Committees.

# Scenario: Under a Microscope?

A researcher has developed a promising gene therapy technique for a pulmonary disease that primarily afflicts children. Although the disease can be managed to some degree through conventional drug therapies, the gene therapy offers the hope of an actual cure.

The researcher heads the Institute of Gene Therapy (IGT) within the School of Medicine and is an NIH-funded researcher on a proposal to conduct a gene therapy clinical trial. She is also the primary stockholder in a private company that has licensed her intellectual property from the University.

The company has been very successful in finding start-up funding and is now providing 25% of IGT's research budget. To help with company fundraising efforts, the researcher routinely travels to the start-up company's Chicago, IL headquarters. The start-up company reimburses her for the travel costs.

After review, the campus COI Review Committee determines that these financial interests can directly and significantly affect the researcher's NIH-supported research. Accordingly they recommend that a plan be put into place to manage the financial conflict of interest.



# Scenario: Under a Microscope? (cont'd)

**Which of the following might be appropriate conflict of interest management/elimination strategies?** (You may select more than one option.)

- a) Disclosure of the researcher's stock ownership when publishing results from the trial.
- b) Divestiture of some or all ownership interests in the company.
- c) Establishment of a committee to monitor the researcher's work on the study.
- d) If one of the researcher's inventions is being tested in the study, naming another faculty member in the school to act as principal investigator on the study.

**Feedback Text**

The best answers are A,B, C, and D. Click the Next button to read a discussion of this scenario.

# Discussion: Under a Microscope?

The Investigator appears to have Significant Financial Interests that could create conflicts with her clinical trial proposal, including stock ownership in a privately held start-up company that conducts research in the same areas as her University research. In addition, the start-up company also provides personal travel reimbursements to the Investigator. Because the Investigator is the inventor of the intellectual property that will be used in the conduct of this clinical trial, an additional level of scrutiny is required.

Because of the number and significance of the Investigator's financial interests, as the trial proceeds, effective management strategies must be employed to protect the human subjects and the integrity of the research. Most campuses will likely require disclosure in publications and presentations and to prospective human research subjects. Some campuses may not permit the inventor to be personally involved in testing that intellectual property when the human subject research is of greater than minimal risk. A combination of strategies is often recommended for more difficult situations such as this and practices vary by location. The COI Review Committee has an important role in conducting case-by-case reviews and in some cases, developing individualized management plans.

# Scenario: Sid's Winter Windfall

Sid is a physician and faculty member in the Division of Endocrinology in the School of Medicine at one of the University campuses. He is an Investigator on a new NIH grant scheduled to start on September 1, 2012. It is a study of 'Preventing Polycystic Ovary Syndrome: a Translational Public Health Approach'. In December 2012, Sid receives a check for \$6,000 from Elsevier. He is thrilled because the unexpected payment couldn't have come at a better time—right before the holidays! It is a royalty payment for a book on 'Addiction Biology' and is the edited proceedings of a conference that he organized as part of his academic career at the University. Sid is the editor of the volume.



**Does Sid need to disclose his windfall from Elsevier to the University?**

- A. Yes
- B. No

Feedback Text

The best answer is A. Click the Next button to read a discussion of this scenario.

# Discussion: Sid's Winter Windfall

The definition of a Significant Financial Interest under the new PHS rules includes income from intellectual property that is not owned by the Regents that reasonably appears to be related to the Investigator's Institutional Responsibilities and that exceeds \$5000 in the prior twelve (12) months. The analysis as to whether Sid needs to report the Elsevier income to the University is three-fold.

## **First, is the intellectual property (copyright, in this case) owned by the University?**

Under University of California policy, faculty are permitted to retain copyright ownership of scholarly works. Since Sid received the royalty check directly from Elsevier, and not the University, we assume that the University does not own the copyright.

## **Second, was the income received from Elsevier related to Sid's Institutional Responsibilities?**

Under the University of California's implementation of the PHS policy, the definition of Institutional Responsibilities includes teaching/education, research, outreach, clinical service, and University and public service performed on behalf of the University of California which are within the course and scope of the Investigator's University of California employment/appointment. Since organization of the conference (public service) that led to the royalty income was done while Sid was a University employee he may need to disclose the income to the University.

## **Finally, does the income exceed \$5000?**

Since the answer to this is 'yes' Sid is expected to disclose this royalty income to the University. The campus will then need to determine whether this Significant Financial Interest is related to his PHS research. In this case, they will most likely determine that it is not. Therefore no further review will be required.

# Conflict of Interest Summary



In today's world, conflicts of interest are inherent in research. As this briefing has shown, conflicts exist in the situations presented and are not dependent on the behavior of the individual. Therefore, managing a specific conflict is not simply a matter of the individual researcher deciding whether a financial interest could compromise his or her research. The institution and the researcher must jointly take the conflict into account when judging its impact on the objectivity of the study.

To perform the necessary review and management of conflicts of interest, relevant financial interests must be disclosed to the University. A fundamental tenet of research integrity is that the methods used and the reporting of results are objective and free from bias. Thus, researchers should always be willing to voluntarily disclose financial interests that could give rise to potential conflicts as a way of protecting the integrity of their work. By doing so, researchers will be able to maintain the public's trust in their own work and in the work of the University.

# UC Policy and Federal Regulations References

Disclosure of Financial Interests & Management of Conflicts of Interest Re: Public Health Service Research Awards

<http://www.ucop.edu/research/policies/integrity.html#coi>

National Institutes of Health, Office of Extramural Research Grants Policy & Guidance

<http://grants.nih.gov/grants/policy/policy.htm>

National Institutes of Health, Office of Extramural Research. Financial Conflict of Interest Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

U.S. Department of Health & Human Services, Public Health Service (2011), 42 CFR 50(f). Responsibility of applicants for promoting objectivity in research for which PHS funding is sought.

[http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)

# UC Conflict of Interest Training for Public Health Service Investigators (COI-PHS)

For additional information and guidance on conflict of interest issues arising in the context of research, please contact your Conflict of Interest Coordinator.

[UC Campus Conflict of Interest Programs](#)  
[UC Campus Academic Conflict of Interest Coordinators](#)

# Certificate of Completion

## University of California Conflict of Interest Training for Public Health Service Investigators (COI-PHS)

Please sign and date this Certification of Completion page below. Please keep a copy for proof of completion of this course for your records, and provide a copy to the Principal Investigator of the project for which training was required.

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By signing and dating this form, I certify that I have read and that I understand the University of California Conflict of Interest Training for Public Health Service Investigators (COI-PHS).

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_