Compliance and Conflict of Interest for Researches Briefing (COIR)
Conflicts of Interest

In the University research setting, financial conflicts of interest can be defined several ways. Having a financial conflict of interest is not wrong. However, a financial conflict of interest may create the appearance of impropriety that can undermine confidence in the conflicted individual or organization. While these conflicts cannot always be avoided, they should routinely be disclosed and a process put in place to manage, reduce or eliminate them if possible.
What is a Financial Conflict of Interest?

American Association of Universities: "...situations in which financial considerations may compromise, or have the appearance of compromising, an Investigator's professional judgement in administration, management, teaching, and the design, conduct or reporting of research results."

Public Health Service and National Science Foundation: A conflict of interest exists when the reviewer(s) "reasonably determine that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of..." the sponsored project.
How are Conflicts of Interest Evaluated?

Disclose:

- Disclose financial interests to the University in accordance with policy.
How are Conflicts of Interest Evaluated?

Review:

- Financial disclosures are reviewed in accordance with UC Policy. Each campus has established an Independent Substantive Review Committee (ISRC) as a mechanism to assess situations where a potential for conflict of interest exists in the design, conduct or reporting of research by virtue of an Investigator’s financial and/or legal ties to the research sponsor or to an entity that could benefit from the research results.
How are Conflicts of Interest Evaluated?

Mitigate:

The ISRC determines whether the disclosed financial interest represents a conflict of interest and if so, whether any management strategies should be implemented to mitigate the potential for the conflicting financial interests to compromise the objectivity in which the project is designed, conducted or reported.
Ultimately, managing a conflict of interest means finding a way to prevent the interest from adversely influencing the research. If conflicts cannot be effectively managed they must be eliminated. Elimination of the conflict may require such measures as divesting equity or resigning from a board.
A Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services such as consulting fees or honoraria, equity interests such as stocks, stock options or other ownership interests, intellectual property rights such as patents, copyrights and royalties from such rights. A Significant Financial Interest is related if 1) it would be affected by the research (or educational activities) funded or proposed for funding, or 2) it is in entities whose financial interests would reasonably appear to be affected by the research.
Disclosure Requirements for Public Health Service (PHS) Proposals and Awards including National Institutes of Health (NIH)

**Investigators:** 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:** 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.

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The Public Health Service initially issued conflict of interest regulations in 1995. In 2011, the regulations were revised in some important ways. The revised PHS regulations went into effect on August 24, 2012. Under these regulations, Investigators are expected to disclose all Significant Financial Interests related to their Institutional Responsibilities. All PHS Investigators should review the Disclosure Of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards.
What am I required to disclose? (Part 4)

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.

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.

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.
Disclosing 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.
Significant Financial Interest and PHS

Significant Financial Interest under the PHS rules means a financial interest of the Investigator (and those of the Investigator’s spouse and dependent children, unless noted otherwise) that reasonably appears to be related to the Investigator’s institutional responsibilities.

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 and dependent children) Significant Financial Interests according to the following timelines.
When do I need to disclose Significant Financial Interests?

- At the time of proposal submission
- Within thirty days of discovering or acquiring any new Significant Financial Interest
- At least annually throughout the period of the award
- Before joining an on-going PHS-funded research project, new Investigators must also complete a disclosure of Significant Financial Interests
How will the University manage my disclosure?

Following receipt of the disclosure of all Significant Financial Interests, a designated official or campus Independent Substantive Review Committee (ISRC) 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 Significant Financial Interest 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 to mitigate the potential for the conflicting financial interests to compromise the objectivity in which the project is designed, conducted or reported.
5. If a conflict is found, the University will report it to the PHS 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 Investigator’s conflict 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: 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.

Each Investigator is required to complete PHS conflict of interest training prior to engaging in PHS-supported research at the University of California at least every four years and under certain conditions. Failure to comply with the requirements of the PHS policy may result in sanctions or discipline per University policy.
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 and 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: Under a Microscope

Dr. Kim heads a gene therapy program at the University and is PI on an NIH-funded proposal to conduct a clinical trial. He also founded a private company that licensed his intellectual property from the University. He holds 20% equity in the company, which reimburses his costs when he travels to headquarters. The campus designated official or COI Review Committee decides that this could affect Dr. Kim’s NIH–supported research.
Scenario: Under a Microscope
Situation: Question and Answer

Question:
What might be appropriate conflict of interest management/elimination strategies?

Please select the best answer or answers:
A. Disclosure of the PI’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 PI’s work on the study.
D. Naming another faculty member to act as Principal Investigator (PI) on the study.

Check your answer
Scenario: Under a Microscope

Question: What might be appropriate conflict of interest management/elimination strategies?

The best answers are:
A. Disclosure of the PI’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 PI’s work on the study.
D. Naming another faculty member to act as Principal Investigator (PI) on the study.

Explanation of the answer:
Dr. Kim has Significant Financial Interests that could create conflicts, including stock ownership and travel reimbursements from a company doing similar research. Because he invented the technique to be used in the clinical trial, additional scrutiny is required. The COI Review Committee has an important role in conducting case-by-case reviews and in some cases, developing individualized management plans.
Discussion: Under a Microscope

Dr. Kim is an employee of the university and a recipient of NIH funding for a clinical trial. This, combined with his ownership and 20% equity in a start-up which has licensed its intellectual property from the university, could create conflicts of interest.
Conflict of Interest Summary

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.
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.
Congratulations!

You've completed the course!

Thank you for completing the UC Conflict of Interest for Researchers briefing. If you have additional questions, seek advice from your Campus Conflict of Interest Program Officer.