



UNIVERSITY
OF
CALIFORNIA

CONFLICT OF INTEREST FOR RESEARCHERS BRIEFING (COIR)

WORKPLACE ANSWERS

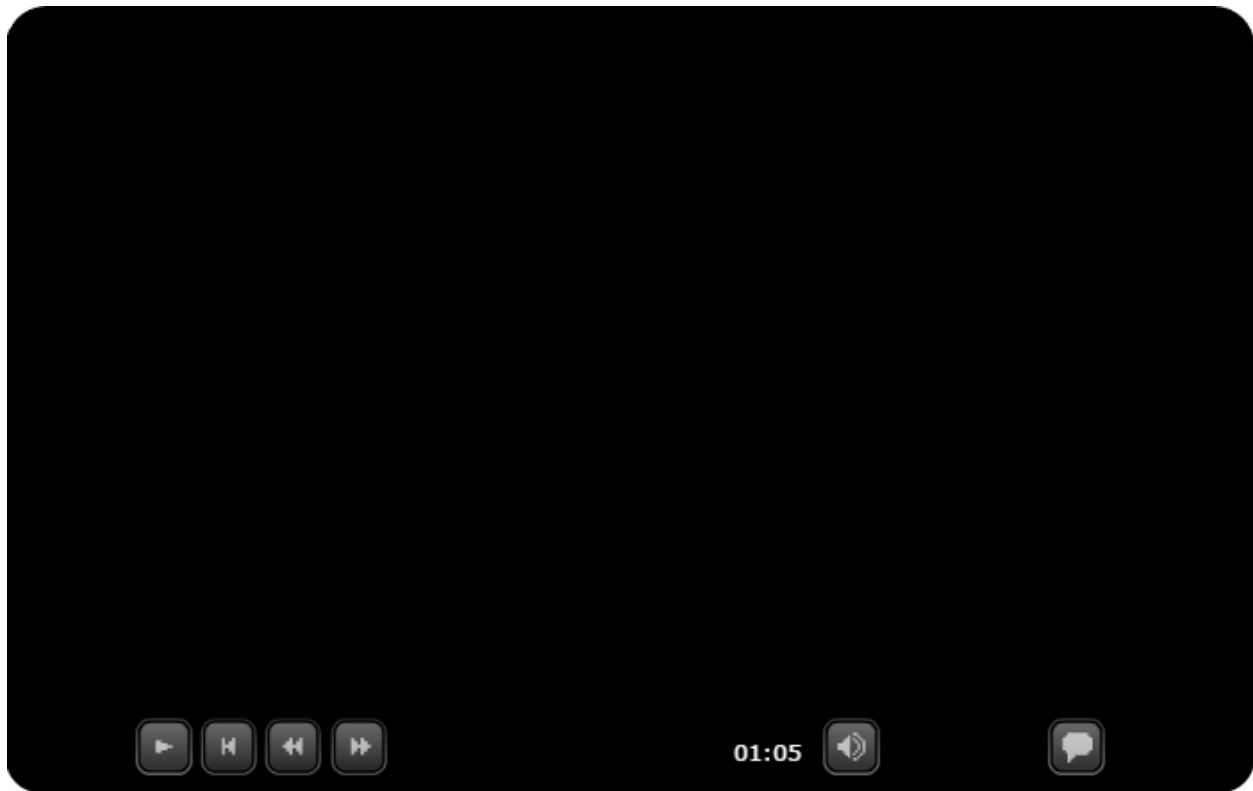
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Compliance and Conflict of Interest for Researches Briefing (COIR)



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Hello. I'm Janet Napolitano, president of the University of California. As a public institution serving and supported by the people of this great state every member of the UC community has a responsibility to conduct themselves in accord with the highest ethical standards. Although laws, rules and regulations help to define appropriate behavior, our ethics and compliance program helps us to apply the rules to particular situations, and to make sure we hold ourselves to the highest standards. Support for our community in doing the right thing is offered through ethics and compliance training and education, such as this program. This education is an important reminder that we must conduct ourselves ethically at all times and is aimed at helping you make good judgements in your daily work. I hope you find it informative. Thank you. And thank you for your service to the University, and to the people of California.

Outline of the Training

This briefing is intended for all University extramurally funded researchers including faculty, staff researchers and postdoctoral scholars, and should take approximately 30-45 minutes to complete. By the end of this briefing, you will have learned:

- About certain expectations and obligations with respect to your University employment.
- About key conflict of interest rules relevant to the University's primary funders of sponsored research.
- How to report potential instances of non-compliance and fraud.

Proceed through the course by clicking the right arrow at the bottom of the page. To mute audio, click the speaker button next to the arrows. If you are in need of accessible links and PDFs, please reach out to your Conflict of Interest (COI) contact.



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Ethical Standards

As members of the University of California community we must be committed to the highest ethical standards to further our mission of teaching, research and public service. We recognize that we hold the University in trust for the people of the State of California. Our policies, procedures and standards provide guidance for application of the ethical values stated in the next page in our daily life and work as members of this community.



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UC Statement of Ethical Values

We are committed to:

Integrity

We will conduct ourselves with integrity in our dealings with and on behalf of the University.

Excellence

We will conscientiously strive for excellence in our work.

Accountability

We will be accountable as individuals and as members of this community for our ethical conduct and for compliance with applicable laws and University policies and directives.

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Standards of Ethical Conduct

Pursuit of the University of California mission of teaching, research and public service requires a commitment to ethical conduct by all. The Standards of Ethical Conduct reflect our belief in ethical, legal and professional behavior in all of our dealings inside and outside the University.

All members of the University community, including The Regents, Officers of The Regents, faculty and other academic personnel, staff, students, volunteers, contractors, agents and others associated with the University are expected to abide by these Standards of Ethical Conduct, which were adopted by The Board of Regents of the University of California, May, 2005.



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Standards of Ethical Conduct List

Listed below are the [UC Standards of Ethical Conduct](#):

- Fair dealing
- Individual responsibility and accountability
- Respect for others
- Compliance with applicable laws and regulations
- Compliance with applicable University policies, procedures and other forms of guidance
- Conflicts of interest or commitment
- Ethical conduct of research
- Records: Confidentiality/privacy and access
- Internal controls
- Use of University resources
- Financial reporting
- Reporting violations and protection from retaliation

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DID YOU KNOW?

The University has comprehensive and interrelated policies and guidelines that address the conduct of researchers, their interactions with private industry, and conflict of interest. The policies work together to set high standards for Investigators, ensure the integrity of research results, and guide interactions of researchers in their partnerships with industry and other University-related activities.



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Research and Integrity

The University's research funding comes from multiple public and private sources. Evidence shows that conflicts of interest may affect research integrity and objectivity.

There are many types of conflict of interest, including conflicts of commitment, personal and institutional financial conflicts of interest, those related to purchasing, use of University facilities, and more. This course will only cover information about personal (or individual) financial conflicts of interest. See [UC Research Conflict of Interest Programs](#). For University policies on other conflict of interest areas please refer to the references at the end of this training.

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What Will This Briefing Cover?

Conflict Types

- Financial Conflicts of Interest

What is a Conflict?

- Definitions and Disclosure Requirements

Who Issues Regulations?

- Federal (PHS, NSF) and State (California)

How are Conflicts Managed?

- Eliminate, Reduce or Mitigate

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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.

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Course Overview

The following section of this briefing includes scenarios that highlight some common financial conflicts of interest at the University of California. These scenarios are meant to highlight some key federal and state rules with which the University and individually funded researchers must comply. Please note that not all conflict of interest requirements by federal or state regulators are covered.



Course Overview

The following section of this briefing includes scenarios that highlight some common financial conflicts of interest at the University of California. These scenarios are meant to highlight some key federal and state rules with which the University and individually funded researchers must comply. Please note that not all conflict of interest requirements by federal or state regulators are covered.

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.

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Who Issues Conflict of Interest Regulations?



UNIVERSITY
OF
CALIFORNIA

The University



The State of California



National Science Foundation



Public Health Service



Who Issues Conflict of Interest Regulations?

The University

The State of California

National Science Foundation

Public Health Service

How are Conflicts of Interest Evaluated?

Disclose:

- Disclose financial interests to the University in accordance with policy.

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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.

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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.

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DID YOU KNOW?

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.



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State of California Disclosure Requirements for Privately Sponsored Research and Research Gifts

Regulations issued by the Fair Political Practices Commission related to the California Political Reform Act require all University employees with “principal responsibility for a research project” to disclose their financial interests in certain non-governmental sponsors of their research. These sponsors include private companies and certain non-profit entities. With each request for research support through contracts and grants, and before gifts earmarked for a specific research project or specific person may be accepted, University researchers must file the [Form 700-U](#) with their respective campuses to disclose their financial interests in the sponsoring entity.

Please also view the [list of non-governmental entities](#) exempt from the disclosure requirement.

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What am I required to disclose? (Part 1)

Investments

A financial interest in the funding entity which totals \$2,000 or more. Reportable investments include, but are not limited to: stock, bonds, warrants, and options, including those held in margin or brokerage accounts. Stocks held in mutual funds do not need to be disclosed.

Income

Any payment from the funding entity which totals \$500 or more during the previous 12 months. Reportable income includes, but is not limited to: salary, dividends, interest, reimbursement for expenses, per diem, loan forgiveness, and payment of indebtedness.

Gifts

Anything valued at \$50 or more for which you have not provided equal or greater consideration to the donor. Commonly reportable gifts include, but are not limited to: tickets/passes to sporting or entertainment events, transportation and lodging, and forgiveness of a loan received by you.

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What am I required to disclose? (Part 2)

Loans: loans received or outstanding from the funding entity if greater than \$500.

Travel Payments: advances and reimbursements provided by the funding entity for travel and related expenses. Depending on the circumstances, a travel payment may be treated as a gift or income.

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Scenario

Election Day

Professor Simon is planning to study electronic voting machines and the accuracy of election results in California. Under the project she will evaluate voting machines produced by two machine manufacturers. Professor Simon does not own stock in either company. However, for the past two years she has received modest fees (\$1,500) from each company for speaking at a conference. One of these companies will be funding her research.

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Scenario: Election Day

Question and Answer:

Is Professor Simon required to disclose the payment in speaker fees on Form 700-U?

Please select at least one answer

- ☐ A. Yes, because the payment exceeds the \$50 threshold for gifts.
- ☐ B. Yes, because the payment exceeds the \$500 threshold for income.
- ☐ C. No, because she has never favored one type of machine over another.
- ☐ D. No, but she should consider it because the company paying her may be affected by the research results.

CHECK YOUR ANSWERS



Scenario: Election Day

Situation: Question and Answer

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The financial interest she discloses will be reviewed to determine whether it constitutes a conflict of interest. In this case, the "perception of a conflict of interest" may be increased because she has been paid by a voting machine manufacturer, and may have publicly supported the use of electronic voting at the conferences.



Scenario: Election Day

The best answer is:

B. Yes, because the payment exceeds the \$500 threshold for income.

Explanation of the answer:

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Discussion: Election Day

WHEN



Research

THEN

Speakers fees

xxxxxx	xxxxxx
Pay to _____	
xxxxxx	_____



Income

Please note!
Please use form 700-u
to disclose income

[Explanation of the diagram.](#)

Discussion: Election Day

In Dr. Simon's situation, when a presentation may equal research, then speaker's fees equal income. Please note that Form 700-U should be used to disclose income.

Disclosure Requirements for National Science Foundation (NSF) Proposals and Awards

1. NSF considers an Investigator to be any individual who shares responsibility for the design, conduct, or reporting of the results of a sponsored project.
2. All Investigators are required to disclose financial interests that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or in entities whose financial interests would reasonably appear to be affected by such activities.
3. Each Investigator is required to disclose all related Significant Financial Interests (including those of the Investigator's spouse, and dependent children).
4. Investigators are required to provide these financial disclosures to the campus before the proposal is submitted to NSF, and whenever they acquire a new Significant Financial Interest during the course of the project. Before joining an on-going NSF-funded research project, new Investigators must also complete a disclosure of Significant Financial Interests.

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What am I required to Disclose? (Part 3)

Based on definitions taken from NSF regulations, UC defines a Significant Financial Interest as anything of monetary value, including, but not limited to:

Income:

- Income from a business entity, including salary, consulting payments, honoraria, reimbursement of expenses, royalty payments, dividends, loans or other payments, including payments made to the Health Sciences Compensation Plan that either exceeded \$10,000 during the previous 12 months or are expected to exceed \$10,000 during the next 12 months. Income received from a public or nonprofit entity for seminars, lectures, teaching engagements, and service on advisory committees or review panels does not need to be disclosed.



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- Intellectual property interest held on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than The Regents.

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DID YOU KNOW?

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Scenario

Green for Forester

Dr. Forester has just received an NSF grant to study bark beetle infestations in trees. For the past ten years, Dr. Forester has been paid \$11,000 a year as a consultant for a large regional lumber company. He advises the company on sustainable timber management, and does not conduct any research relating to his NSF grant.



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Question and Answer:

Which of the following is likely Dr. Forester's most appropriate course of action?

Please select at least one answer

- ☐ A. He should have disclosed his consulting work and income to the University before the NSF proposal was submitted.
- ☐ B. He should suspend his consulting activities.
- ☐ C. He does not need to disclose it because the consulting does not directly relate to the NSF grant topic.
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CHECK YOUR ANSWERS



Scenario: Green for Forester

Situation: Question and Answer

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At the time of proposal submission, Investigators are required to disclose Significant Financial Interests. Dr. Forester's income from the lumber company (\$11,000) exceeds the NSF threshold of \$10,000. Although the scenario does not appear to constitute a conflict of interest as defined by NSF regulations, Dr. Forester's paid consulting activities still might raise concerns. He should disclose his consulting work for the company in any publications or presentations he makes based on this research. The COI Review Committee or campus designated official(s) may make a range of different recommendations depending on the facts of the specific case.

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Scenario: Green for Forester

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Explanation of the answer:

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Discussion: Green for Forester?



[Explanation of the diagram.](#)

Discussion: Green for Forester?

Dr. Forester is involved with consulting for the lumber company, while also being employed by the university, which could cause conflicts of interest.

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](#).



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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.



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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.

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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.

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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

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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.



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PHS: Reporting Conflicts of Interest 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 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.

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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 PHSPHS-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.



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PHS: 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 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.



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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.



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Scenario: Under a Microscope

Question and Answer:

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

Please select at least one answer

- ☐ 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 on the study.
- ☐ D. Another faculty member should be named Principal Investigator (PI) on the study.

CHECK YOUR ANSWERS



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.
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Check your answer

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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.



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Question:

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Explanation of the answer:

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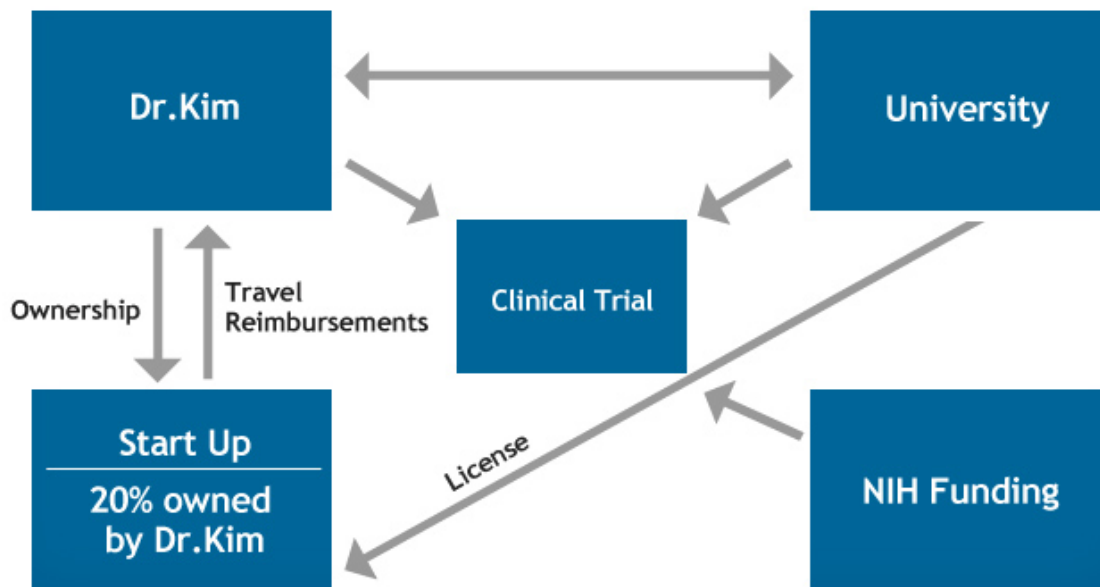
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Discussion: Under a Microscope



[Explanation of the diagram.](#)

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.

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Working Together

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.

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Reporting Improper Activities

The next section of the course covers how to report improper activities and your obligations as a University of California employee:

- Illegal activities and significant policy violations should always be reported in accordance with applicable laws and policies.
- The University is committed to responsible evaluation of all reports of violations of the Standards of Ethical Conduct and/or alleged improper activities on the part of members of the University community.
- The University has established processes for reporting and investigating any suspected wrongdoing, including an anonymous hotline people are encouraged to use if they don't feel comfortable bringing the matter forward openly (see [UC Whistleblower Hotline](#)).
- An individual who is made aware of an improper act should consult with someone at a higher level of authority or with the Locally Designated Official (LDO) to determine how to handle the matter.

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Decision Tree for Reporting Compliance Concerns (Part 1)

Your immediate supervisor is your primary reporting option.



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Decision Tree for Reporting Compliance Concerns (Part 2)

If hesitant to report to your supervisor, you may report to one of these resources:

Campus Ethics
and Compliance
Officer

Human
Resources

Campus
Counsel

Locally
Designated
Official

Decision Tree for Reporting Compliance Concerns (Part 2)

If hesitant to report to your supervisor, you may report to one of these resources:

Campus Ethics and Compliance Officer

Human Resources

Campus Counsel

Locally Designated Official

Decision Tree for Reporting Compliance Concerns (Part 3)

If hesitant to report locally, you may report to a systemwide resource:

Chief Compliance
and Audit Officer

UC Whistleblower Hotline:
(800) 403-4744
(anonymous/confidential)



Decision Tree for Reporting Compliance Concerns (Part 3)

If hesitant to report locally, you may report to a systemwide resource:

Contact Info

[Locally Designated Officials \(LDO\)](#)

[Campus Ethics and Compliance Officers \(CECO\)](#)

[Campus Counsel](#)

Chief Compliance and Audit Officer 510-987-9090

[UC Whistleblower Hotline \(anonymous/confidential\)](#) or (800) 403-4744

[UC Campus Climate Reporting](#)



Your Employment Obligations

As an employee of the University of California, it is important that you:

- Know the applicable laws, regulations and policies that affect your employment responsibilities.
- Understand the Statement of Ethical Values and Standards of Ethical Conduct and University policies and procedures related to your employment responsibilities.
- Ensure your actions are consistent with the Statement of Ethical Values and Standards of Ethical Conduct.
- Report potential instances of non-compliance and fraud.
- Understand your rights and responsibilities under the [UC Whistleblower Policy](#) and the [UC Whistleblower Protection Policy](#).

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University of California Policies

[University of California Policy - Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards](#)

[University of California Policy - Disclosure of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards](#)

[APM 016 - University Policy on Faculty Conduct and the Administration of Discipline](#)

[APM 025 - General University Policy Regarding Academic Appointees: Conflict of Commitment and Outside Activities of Faculty Members](#)

[APM 028 - General University Policy Regarding Academic Appointees: Disclosure of Financial Interest in Private Sponsors of Research](#)

[APM 670 - Salary Administration - Health Sciences Compensation Plan](#)

[APM 671 - Salary Administration - Conflict of Commitment and Outside Activities of Health Sciences Compensation Plan Participants](#)

[Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research](#)

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](#).

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