

What Is an Interest?

Researchers may have many different interests that motivate them to perform their work. These interests may include:

The advancement of knowledge generally or specific benefits for individuals or society;
Professional advancement; and

Personal gain. These interests are all legitimate and justifiable incentives to perform research. Often these interests may be mutually reinforcing. A researcher who discovers a new vaccine will produce direct societal benefits but will also receive significant reputational and perhaps economic benefits as well.

What Is a Conflict of Interest?

Researchers' interests can and often do conflict with one another. For example, the advancement of knowledge is usually best served by sharing ideas with colleagues so that each may contribute to new developments. But personal gain is sometimes best served by not sharing ideas until they are fully developed and then protected through patents, copyrights or publications.

These competing responsibilities are commonly called conflicts of interest. As one author has noted, "A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual." Having an interest relating to the research is not inherently wrong. The complex and demanding nature of research today inevitably gives rise to situations in which a researcher's various obligations and interests may compete. Conflicts cannot always be avoided but, at a minimum, they must be reviewed and addressed.

Commonly used definitions of conflicts of interest include:

- ◆ Conflicts of interest are "situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgment in conducting or reporting research" (Association of American Medical Colleges, 1990).
- ◆ "A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance compromise the integrity of the research" (National Academy of Sciences, Integrity in Scientific Research).
- ◆ "No public official at any level of state or local government shall make, participate in making or in any way attempt to use their official position to influence a governmental decision in which they know or have reason to know that they have a financial interest" (California Government Code section 87100).

Financial Conflicts of Interest

Financial conflicts of interest are situations that create perceived or actual tensions between personal financial gain or loss and adherence to the fundamental values of honesty, accuracy and objectivity.

As in the case of other conflicts, holding financial interests related to research is not inherently wrong. Researchers are permitted to benefit financially from their work. In 1980, Congress passed the Bayh-Dole Act, which encourages researchers and research institutions to use copyrights, patents and licenses to translate research ideas into technologies and products that can benefit the public. It not only approves of, but strongly encourages researchers and research institutions to have financial interests as a way of ensuring that the public investment in research leads to economic growth.

Federal Conflict of Interest Requirements

Because of the concerns about financial conflicts of interest affecting research outcomes, many federal granting agencies have established conflict-of-interest rules. The rules of the Public Health Service, which includes the National Institutes of Health (NIH), and the National Science Foundation (NSF) are typical and apply to much of the University's federal research.

Under these regulations, and as explained in the following pages, the University has established administrative procedures to take all of the following steps:

- ◆ Report significant financial interests before any research is undertaken.
- ◆ Manage, reduce or eliminate significant financial conflicts of interest.
- ◆ Provide subsequent information to the funding agencies on how the conflicts were handled.

These procedures are implemented by the campus Conflict of Interest Committee.

Significant Financial Interest under Federal Rules

Significant financial interests are defined to be anything of monetary value above a certain threshold in a company or entity engaged in work that appears reasonably related to the research. These include:

- ◆ A salary or other payments for services (such as consulting fees or honoraria) **of more than \$10,000** in a single year.
- ◆ An equity interest (such as stocks, stock options or other ownership interests) that
 - ◇ **exceeds \$10,000** in fair market value, or
 - ◇ represents an ownership interest greater than 5 percent in a single entity.
- ◆ Intellectual property rights (patents, copyrights or royalties from such rights).
- ◆ A management position in a company or other entity, such as board member, director, officer, partner or trustee.

A "significant financial interest" does not include **any** interest above these thresholds in any company – it only applies to those related to the research. Certain agencies, such as the Food and Drug Administration, may have more stringent thresholds. It is also important to note that these disclosure obligations apply to the research team, not just the principal investigator.

An Affair of the Heart

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

Dr. De la Couer is a principal investigator on an NIH grant that is supporting his work on an experimental gene therapy program for heart disease victims at a University medical center. Because the program looks quite promising, Dr. De la Couer has formed a corporation with some other researchers and investors called Heart Genetics, Inc. (HGI) to commercialize the research. Should the therapy prove to be successful, HGI could become very profitable. Dr. De la Couer owns 20 percent of HGI. A colleague of Dr. De la Couer recommends a patient to him for purposes of receiving the experimental gene therapy. Dr. De la Couer enrolls the patient as a subject in his NIH study.

An Affair of the Heart

Question

Does the doctor's ownership interest have to be disclosed to the University and/or to the patient?

The best answer is

- A. Yes, it must be disclosed only to the University.
- B. Yes, it must be disclosed only to the patient.
- C. Yes, it must be disclosed to both.
- D. No, it does not have to be disclosed to either one.

Tsunami Test

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

The NSF has funded a study to develop a prototype of a low-cost seismographic instrument that could be deployed off the coast of the Pacific Ocean to refine predictions of tsunami events caused by earthquakes around the Pacific Rim. Professor Richter in the Department of Electrical Engineering was selected to be the principal investigator on the study and has been working with a colleague in the Oceanography department on a conceptual design for such an instrument.

Professor Richter believes that this project would be a perfect test for some instruments in development at his own company, which he spun off from his University research almost a decade earlier. The company is privately-held by the professor and two other investors, each of whom hold one-third of the company's stock. Although it has yet to bring a product to market, the company holds a number of patents that build on patents Professor Richter obtained before coming to the University. There has been some limited venture capital interest in the company, which received \$1 million in new funding shortly after the Banda Aceh, Indonesia tsunami in 2004. The professor believes that if the NSF project successfully demonstrates the value of the technology, the value of his company's patents might increase substantially and could attract additional funding.

Tsunami Test

🕒 **Question**

Does the professor's interest in his company qualify as significant financial interest?

🕒 **The best answer is**

- A. Yes, the value of his stock and patents appears to exceed \$10,000, and he has an ownership interest in one-third of the company.
- B. No, the stock is not publicly traded and therefore does not have a fair-market value exceeding \$10,000.
- C. No, the value of the patents cannot be established before the successful test of the NSF project.

California Academic Financial Interest Disclosure

In addition to the federal conflict-of-interest requirements, UC researchers must also follow California law on disclosing relevant financial interests that may arise in the context of academic research.

Under the California Political Reform Act, UC must review certain financial interests of principal investigators when the project is funded or supported by a nongovernmental entity, such as a private company. UC researchers file information about financial interests on the [Form 700-U](#) with the campus. Research funding by [certain nonprofit entities](#) will not trigger disclosure.

The financial interests required to be reported include investments, management positions, income, loans, gifts and travel payments when those interests are held in, or payments are made by, a research sponsor.

Financial Interests under California Law

The definitions of financial interests under California law are different, and in most cases more stringent, than the definitions of significant financial interest under federal law. The following interests are covered under the California definitions and must be disclosed when they involve the entity sponsoring the research:

Investment – Any financial interest in a business entity held by the researcher or his or her immediate family which totals \$2,000 or more.

Income – Any payment including salary, wages, advances, proceeds from sale or loan which totals \$500 or more.

Gift – Anything of value for which the researcher has not provided equal or greater consideration to the donor, including items of value such as loan forgiveness. The gift is reportable if its value is \$50 or more. As of January 1, 2007, University employees may not accept gifts that exceed \$390 from a single source.

Travel Payments – Advances and reimbursements for travel and related expenses, including lodging and meals. Depending on the circumstances, a travel payment may be treated as income or a gift.

Management Position – Such as board member, director, officer, partner or trustee held by the investigator.

Election Day

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A faculty member in the Political Science Department, Professor Pam Beach, is planning to study the use of electronic voting machines and their effect on elderly voter turnout in California. Her project will require her to review current voting trends and to evaluate the ease of use of voting machines produced by the two main machine manufacturers. Professor Beach does not own stock in either company, but she has received modest fees from one of the companies for speaking at annual conferences held for county registrars for the past two years, and that company will be providing some of the funding for her research.

She has been scrupulously fair to make sure that her presentations to the registrars do not favor one machine over the other, although she has openly stated her belief that electronic voting will produce more accurate election results. Her exchanges with the registrars at the conferences have been intellectually valuable but not especially lucrative, and she has been paid \$600 each year in speaking fees.

Election Day

Question

Does Professor Beach have to disclose the payment in speaking fees on a Form 700-U?

The best answer is

- A. Yes, the payment exceeds the \$50 threshold for gifts.
- B. Yes, the payment exceeds the \$500 threshold for income.
- C. No, she is not required to report it, but she should strongly consider reporting because the payments came from a voting machine manufacturer – a party that may be affected, directly or indirectly, by the results of her research.
- D. No, she doesn't have a conflict of interest because she has never favored one type of machine over another.

April in Paris

🎯 Situation

The Population Council has scheduled a springtime conference in Paris for researchers working on HIV- and AIDS-prevention issues in Africa. A University researcher has been invited to attend the conference, all expenses paid. The offer includes airfare and the cost of the hotel and all meals.

🎯 Question

Does the cost of the trip have to be disclosed on the Form 700-U?

🎯 The best answer is

- A. Yes, the costs of travel are a gift where no service is being provided.
- B. No, the costs do not have to be declared if the Population Council is a qualifying exempt organization.

A Free Lunch?

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A drug company contacts Dr. Mittagessen, a principal investigator whom they routinely support, to sponsor a lecture series for the researchers on its clinical trials. Other than providing the food to the researchers, the company exercises no control over the event; the department determines the topics. There are no speaker expenses because all of the speakers are members of the faculty.

The total cost of the food over the year is not excessive, but it does add up. The cost to provide lunches for the 15 researchers last year was \$2,250.

A Free Lunch?

Question

Do the "free lunches" have to be disclosed by Dr. Mittagessen on the Form 700-U?

The best answer is

- A. Yes, the lunches are a gift from a sponsor.
- B. No, the lunches are unrelated to the research and merely facilitate a departmental function.

Another Free Lunch?

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

The same drug company thinks that the lecture series is going so well that they decide to provide funding to the department for a departmental lunch. The company pays the department for the food and gives \$750 to the department for each guest lecture. The department selects the lecturers without consulting the drug company or using a list provided by the company. Dr. Mittagessen is selected to provide one of the upcoming lectures.

Another Free Lunch?

Question

Does the lecture fee have to be disclosed on a Form 700-U by Dr. Mittagessen?

The best answer is

- A. Yes, the payment counts as indirect income to Dr. Mittagessen from the sponsor above the \$500 limit.
- B. No, it is not income from the sponsor because the payment comes from the department.

Buying Advice in Biopolis

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A drug company has established a large biotech research and development campus in the Biopolis section of Singapore. In anticipation of receiving a proposal from a faculty researcher, it invites him to visit its facilities to review and comment on a product, discuss independent research projects and explore the potential for collaborative research.

The company offers to pay all of the travel expenses for the Singapore trip.

Buying Advice in Biopolis

Question

If the company decides to fund the investigator's proposal, will he need to disclose the travel expenses on the Form 700-U?

The best answer is

- A. The travel expenses are reasonable compensation for the time and inconvenience of the travel. No disclosure is required.
- B. The travel expenses are a gift.

Journal Policies on Conflicts of Interest

For a number of years, professional and scholarly journals have required the disclosure of financial and other relevant interests. Although certain organizations, such as the International Committee of Medical Journal Editors and the Council of Science Editors, have worked to establish consistent standards for definitions and disclosures of these interests, researchers must check the policies of each specific journal before submitting manuscripts.

Relevant financial interests may be defined different ways by different publications. In addition, the journals may allow different methods of disclosure. Some authors completely disclose all relevant interests in the submitted manuscript itself, other authors disclose relevant interests in a cover letter or in the authorship form. Some publications require that such interests be disclosed, others only request it.

Example of Journal Policy

In response to recent news stories about undisclosed conflicts from study authors, the Journal of the American Medical Association (JAMA) revised its COI policy in 2006.

Under the JAMA policy, "A conflict of interest may exist when an author (or the author's institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work or manuscript."

JAMA policy requirements:

- ◆ Authors are expected to provide detailed information about all relevant financial interests and relationships within the past 5 years and for the foreseeable future – particularly those present at the time the research was conducted and through publication – that represent potential future financial gain.
- ◆ JAMA will require that all COI disclosures be listed in the Acknowledgment section at the end of the manuscript.

Soy Situation

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

Dr. Midland has worked for a number of years on studies describing the various nutritional benefits of soy products as a substantial part of a daily diet. This work has been supported by grants from several different federal agencies ranging from the NIH to the U.S. Department of Agriculture.

In addition to his research, Dr. Midland has also been hired from time to time by several food manufacturers to comment on the nutritional claims they propose to make in their advertising and promotional materials for their products. For this work, Dr. Midland generally charges a small fee for each task, and has never charged more than an aggregate amount of \$2,500 in a single year. His last job of this kind was four years ago.

Dr. Midland is pleased to find that his most recent article has been accepted for publication by the Journal of the American Medical Association. He understands that JAMA would like to review potential conflicts of interest, but he is not sure how and what to report to JAMA.

Soy Situation

Question

What should Dr. Midland report to JAMA?

The best answer is

- A. The consulting work for the food companies is unrelated to his research on soy products and need not be reported.
- B. The consulting work is above the \$500 income limit for state reporting, but it is below the \$10,000 limit for federal reporting. Because his work was funded by federal agencies and the amounts were below the applicable limit, no conflict of interest reporting is required.
- C. The consulting work for the food companies should be reported.

Managing Conflicts of Interest

If a researcher has a financial interest that is related to his or her research, as defined by federal or state rules, the interest must be reported to the campus COI committee and the committee will determine whether a conflict of interest exists that must be reduced, managed or eliminated. "Managing" a conflict means finding ways to assure that the interests do not adversely influence the research.

These can include any or all of the following steps:

- ◆ Requiring full disclosure of all interests so that others are aware of the potential conflicts and can act accordingly.
- ◆ Monitoring the research or checking research results for accuracy and objectivity.
- ◆ Removing the person with the conflict from crucial steps in the research process, such as the interpretation of data or participating in a particular review decision.

Managing Conflicts of Interest

If the conflicts cannot be managed and could have an adverse impact on the research, they must be eliminated or reduced to acceptable levels by any of the following methods:

- ◆ Divesting equity.
- ◆ Reducing the income received from the sponsor of the research.
- ◆ Assigning supervisory responsibilities to another investigator.

The COI committee – not the researcher – makes the final decision about the management of COI.

Green Forests Lead to Green for Forester

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A professor in the College of Environment and Natural Resources has just received a three-year grant from the NSF to study certain sustainable forestry practices in Oregon and Washington. In the past, the professor's work has been the subject of much discussion and debate by environmental groups, forest product companies and the U.S. Forest Service.

For the past 10 years, the professor has been paid \$3,000 a year to serve as a consultant to one of the largest lumber companies in the Pacific Northwest and has received stock that has fluctuated over time but is now worth \$15,000. The consulting work involves advice to the company on timber harvests and forest regeneration generally but does not include the practices he is researching for the NSF. In addition to supplementing his University salary, the consulting work has given him the valuable opportunity to observe, over time, some of his recommended practices used in the field over mass acreage.

Green Forests Lead to Green for Forester

Question

Which of the following should the conflict-of-interest committee recommend as the most appropriate management strategies?

The best answer is

- A. The professor should disclose his stock ownership and consulting work for the lumber company to his University research group and in publications and presentations on his research.
- B. The professor should reduce his stock ownership in the lumber company to below \$10,000 for the period of the NSF study.
- C. The professor should suspend his consulting activities and sell all his stock in the company.
- D. The dean of the college should monitor the professor's work on the study.
- E. Another faculty member should be named to be the principal investigator on the study.

NeoGen

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A principal investigator (PI) has developed an innovative gene-therapy technique that offers exceptional promise for people afflicted with a disease that is particularly prevalent among 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 PI heading the study also heads the Institute of Gene Therapy (IGT) within the school of medicine. The PI has also started a company called NeoGen to bring the PI's discoveries to market; she is the primary stockholder. NeoGen has been very successful in finding start-up funding and is now providing 25 percent of IGT's budget. The PI is interested in running a clinical trial at the University on a prototype therapy from NeoGen.

NeoGen

Question

Which of the following should the conflict-of-interest committee recommend as the most appropriate management strategies?

The best answers are

- A. The professor should disclose her stock ownership on any publications that may result from a successful trial.
- B. The professor should reduce her stock ownership in NeoGen to below 5 percent of the total outstanding shares during the clinical trial.
- C. The professor should divest all ownership interests in NeoGen.
- D. A committee should be established to monitor the PI's work on the study.
- E. Another faculty member in the school should be named to be the principal investigator on the study.

Conflicts of commitment arise from situations that place competing demands on researchers' time and loyalties. Researchers engage in many activities, including:

- ◆ Working on one or more funded projects.
- ◆ Teaching and advising students.
- ◆ Attending professional meetings and giving lectures.
- ◆ Serving as a peer reviewer.
- ◆ Working as a paid consultant, officer or employee in a private company.

Each of these activities requires time and imposes demands on a researcher's institutional commitments. Researchers need to make sure that outside activities do not interfere with these commitments.

Under University policy, researchers may devote the equivalent of one day per week to outside professional activities. These activities can often provide benefits to the researcher, his or her students and the University in general. However, in pursuing such activities, care must be taken to avoid certain common conflicts.

Serving Two Masters



Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

Dr. Divisio works in the Department of Computer Science. In addition, she works as a consultant for a large electronics company on the integration of various types and levels of operating systems for consumer electronic devices. This work provides her with valuable insight into cutting-edge technologies used in the electronics field and enables her to see some of her advanced concepts come to fruition in the marketplace.

Although she tries to limit her time on this outside consulting work to approximately one day per week, the work is also financially beneficial to her, providing her with over \$180,000 per year in outside income. This is more than her University salary, and the job appears to occupy much of her attention. Since beginning this consulting project, she has stopped attending faculty meetings and has nearly eliminated her office hours available for meeting with students.

Serving Two Masters

Question

Does Dr. Divisio need to modify her work practices to comply with the University's conflict-of-commitment policy?

The best answer is

- A. No, although she is understandably enthusiastic about her outside projects, she is still performing within the guidelines set forth in University policy.
- B. Yes, Dr. Divisio has a conflict of commitment and is not fully performing her University duties.

Mentoring of Students

Researchers involved in start-up ventures often have opportunities to hire students, including their own. As mentors, they have a primary obligation to help students develop into independent researchers. As heads of start-up companies, their primary obligation is to see promising ideas commercialized. Under University policy, the researcher's duty as a faculty member responsible for guiding the student's work takes precedence over the commercial considerations of the company.

Keeping It in the Nuclear Family

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

A PI in the School of Nuclear Engineering has developed a new predictive model using computer simulations based on radiography of pipes in nuclear power plants to determine when a pipe is likely to fail. Although the PI is an expert in the radiography analysis, the key breakthrough came from algorithms developed by his most promising graduate student.

The PI believes that global warming concerns will lead to an increased interest in using nuclear power as a source of electricity, and he has started a company to perform the failure analysis for utility companies around the country. He has proposed a research project funded by his start-up company. In his disclosure to the campus COI committee, he notes that he would like to hire his graduate student to assist with the work.

Keeping It in the Nuclear Family

Question

May the PI's company hire the graduate student?

The best answer is

- A. Yes, in fact the PI should be encouraged to find similar "real world" experiences at the cutting edge of technology for other students.
- B. Not without prior approval from a delegated campus official, and this approval is rarely granted.

Use of Laboratory Resources

Equipment, supplies and University facilities purchased with public funds can easily be used to advance private research interests. While this might seem like a harmless practice – particularly if the equipment is not in constant use – the equipment and supplies remain the property of the University of California.

Thank You, Mr. Chips

Read the following scenario and consider the rules or principles that apply. We'll ask you a follow-up question on the next page.

Professor Chipping has been committed to improving science education in grades K-12 for many years. He lives in a city with a large, urban public school district, and his wife is a chemistry teacher at a nearby high school. From time to time, Professor Chipping provides seminars to the advanced students at the school. During his visits, he notices that the classes not only lack enough science textbooks for each of the students, but often lack basic laboratory equipment.

To assist the underfunded local schools, Professor Chipping starts bringing in old computer equipment, Bunsen burners, beakers and other glassware. This gives him the opportunity to improve a local school while clearing surplus equipment out of his University lab.

Thank You, Mr. Chips

Question

Is Professor Chipping allowed to donate his lab's equipment to his wife's high school science class?

The best answer is

- A. Yes, this is a win-win situation that benefits needy students and helps the University deal with surplus property.
- B. No, the lab equipment is not his personal property and must be disposed of in accordance with University policy.

Conclusion



Conflicts of interest are inherent in modern research. As stated earlier, the conflicts lie in the situations presented and are not dependent on the behavior of the individual. Therefore, managing an individual conflict is not simply a matter of an 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 the validity of the study.

To perform the necessary review and management of conflicts of interest, financial or other relevant interests related to the research must be disclosed. 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 interests that could give rise to potential conflicts as a way of protecting the integrity of their work. By so doing, researchers will be able to maintain public trust in their own work and in the work of the University.

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