

Conflicts of Interest and Commitment



Office for the Protection of Research Subjects (OPRS)

*Dalar Shahnazarian, MSW Candidate, IRB Student Mentor;
Susan L. Rose, Ph.D.; Jennifer Hagemann, MS; Monica Aburto*

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About the Source Material

The Collaborative Institutional Training Initiative (CITI) web based education program, developed by the University of Miami and the Fred Hutchinson Cancer Research Center, offers training in Human Subjects Research, the Responsible Conduct of Research, and Good Clinical Practice. CITI is currently used by over 1130 participating institutions and facilities from around the world and offers online course material in more than seven different languages. CITI RCR was developed with public funds and thus allowed access to material used to create these booklets.

Introduction to Conflict of Interest and Commitment

Trust is essential in scientific pursuit of knowledge. The University of Southern California, the public, and the academic community all trust that research will be conducted objectively in the interests of scientific advancement and public welfare. A relationship based on trust must exist between researchers and colleagues, the government, study sponsors, and the public.

Objectivity is fundamental to this trust. In order to maintain that trust it is important to understand the policies regarding identification and management of conflicts of interest. This booklet presents an overview of conflicts of interest as well as case studies and several reference lists.

What is Conflict of Interest?

In the research environment, a Conflict of Interest (COI) exists when a researcher's personal interests, such as career, reputation, or finances, may or do conflict with his/her professional obligations to conduct honest, objective research activities. COIs that go unmanaged may lead to a loss of confidence in the integrity of the researcher, data, and research institution. They can also lead to injury or harm to study participants or the patients who may use a product wrongly approved. COIs reduce the trust and confidence that people generally have in the pursuit of research.

Definition of a Conflict of Interest

The University of Southern California defines Conflict of Interest as “*a situation in which financial or other personal considerations compromise, or have the appearance of compromising an individual's professional judgment in proposing, conducting, supervising or reporting research*”.
([USC Conflict of Interest in Research Policy](#))



The **appearance of a conflict of interest** exists when a reasonable person would think that the professional's judgment is likely to be compromised. A conflict of interest only implies the potential for bias. It is important to note that ***a conflict of interest exists whether or not decisions are affected by personal interest.***

While conflicts of interest apply to a wide range of behaviors, they all involve the use of a person's authority for personal/financial gain.

COIs are broadly divided into two categories:

- **Intangible-** those involving academic activities and scholarship
- **Tangible-** those involving financial relationships

Intangible Conflicts of Interest

Bias can creep into how research questions are selected and framed, the choice of research design, the selection of research participants, and how the data are collected, interpreted, and ultimately published. In an effort to succeed, a researcher's judgment and objectivity can become clouded by bias. Objectivity in research can be compromised by:

- Internal or external pressures to get a specific result
- Ruling out data that do not support a hypothesis
- A desire to validate a belief

Intellectual Bias

An **academic conflict of interest** could occur if an individual interferes with the peer-review process for personal gain. Bias can cause a reviewer to respond positively to a manuscript because it presents results favoring a method or production in which the reviewer has a personal interest. Alternatively, a biased reviewer may act to delay the publication of a competitor's manuscript in order to strengthen his or her own chances for publication or funding.

Financial or Tangible Conflict of Interest

A tangible COI exists when a financial payment or monetary reward may influence an individual to prefer one outcome over another. The following are examples of financial interests which must be disclosed before a researcher can begin or continue an investigative enterprise:

- When a researcher holds an equity interest (such as stocks) in a sponsor or company that has an economic interest in the specific research
- When a researcher holds a management role in (e.g. significant decision making authority) a sponsor or company that has a significant economic interest in the research.
- When students of a researcher perform services for a company in which the investigator, research personnel, or close relation of either, has an ownership or management role *and* has the ability to influence the academic progress of the student.

Research for Public Good

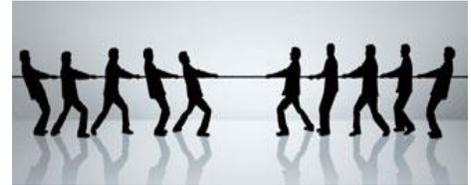
Financial interests are not inherently wrong. Researchers are permitted to benefit financially from their work. A 1980 Congressional law known as the Bayh-Dole Act encourages researchers and research institutions to use copyrights, patents, and licenses to put research ideas to use for the good of the public. Prior to this time, there were no uniform policies regulating the ownership of ideas developed with public funding. Bayh-Dole essentially gives that ownership to research institutions as an incentive to put ideas to work for the overall good of society. It not only approves of but, in fact, strongly encourages researchers and research institutions to have financial interests as a way of ensuring that the public's investment in research is used to stimulate economic growth.¹

¹ “*ORI Introduction of the Responsible Conduct of Research*” (2007). Nicholas H. Steneck

Conflicts of Commitment

Conflicts of commitment arise from situations that place competing demands on researchers' time and loyalties. At any time, a researcher might be:

- working on one or more funded projects
- preparing to submit a request for a new project
- teaching and advising students
- attending professional meetings and giving lectures
- serving as a peer reviewer
- sitting on advisory boards
- working as a paid consultant, officer, or employee in a private company



Each of these activities requires time and makes demands on a researcher's institutional commitments. Care needs to be taken to assure that these commitments do not inappropriately interfere with one another.²

Start-Up Ventures and Relationships with Students

Academic researchers involved in start-up ventures often have opportunities to hire students. This puts them in a situation where they can hire their own students. 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. While the two responsibilities can complement one another, they can also be in conflict. Should an individual who is both the researcher's student and employee be advised to develop a promising idea that could lead to an independent career or to work on a more routine problem that will benefit the start-up company? Situations such as these create conflicts and should be avoided or appropriately managed.²

² “*ORI Introduction of the Responsible Conduct of Research*” (2007). Nicholas H. Steneck

Conflicts of Interest in Clinical Research

Clinical researchers subscribe to three basic principles:

- Pursuit of knowledge
- Patient safety
- Investigator objectivity

Bias and decreased objectivity are especially dangerous in the clinical-research setting where the rewards and risks are potentially great. In the clinical setting, bias and loss of objectivity can damage the entire research enterprise, thus reducing the public's trust in research. It can also lead to injury and harm to study participants.



Two examples of financial COIs in research ethics include:

- Jesse Gelsinger and University of Pennsylvania gene therapy clinical trial (1999)
- [Thomas R. Insel, director of NIMH \(National Institute of Mental Health\) \(2010\)](#)

The clinical investigators in both studies were so caught up in the scientific aspects of their projects that they ignored the welfare of the participants in these studies and ultimately harmed them.

Addressing Conflicts of Interest

The University of Southern California encourages its faculty, staff, and students to participate in meaningful professional relationships with industrial, government, and private partners. These partnerships frequently produce knowledge and intellectual property that is beneficial to society. However, USC faculty, staff, and students must be cognizant of the conflicts of interest that may arise from these relationships.

USC's Conflict of Interest Policies and Procedures outline three steps for addressing COIs: **Identification**, **Disclosure**, and **Action**.

Identification

Each researcher is responsible for determining whether he or she, or his/her close relation (spouse, domestic partner, or dependent child) has a potential Conflict of Interest or Commitment. The Office of Compliance, the Offices of the



Vice President for Research, and the Dean or Associate Dean for Research at USC are all available to assist in the COI identification process.

Faculty, staff, and students must be familiar with USC's Conflict of Interest in Research: Policy and Procedure and to be able to recognize COIs.

(http://policies.usc.edu/p4acad_stud/conflic_interest_research.html)

Disclosure

USC provides investigators with clear mechanisms for the disclosure of actual or apparent COIs such as the *Statement of Outside Interests Related to Research* (<http://dcg.usc.edu/Propprep/wordfiles/outinter.dot>). COIs are reviewed by the Vice President for Research and the Conflict of Interest Review Committee (CIRC). Given the complexity of financial and non-financial relationships within the university, each association is evaluated on a case-by-case basis to determine if it constitutes a Conflict of Interest and how it should be managed.

Action

The University addresses COIs through management of the relationship or research or outright prohibition of the proposed conflicting relationship. Many COIs can be managed, reduced, or eliminated by the university or departmental evaluation. Once the COI has been presented to Vice President for Research and the CIRC, the research may be:

- Permitted as is
- Permitted contingent upon the implementation of one or more actions for managing the COI
- Prohibited

Managing Conflicts of Interest

Disclosure and oversight of the research are the most common management strategies implemented by the CIRC. Specific steps might include:

- Disclosing the investigator's financial interests with the sponsor to any human research volunteers
- Requiring the investigator's financial relations to the sponsor be included in all written and oral presentations, publications, and abstracts
- Prohibiting use of students in the research



Depending on the seriousness of the conflict, other management strategies could include:

- Modifying the research plan, including changing the site(s) of the trial
- Monitoring research via independent reviewers. This could include special oversight and approval of any consulting agreement language when faculty consults with companies in which they also hold equity interests. In a clinical study, oversight could include participant recruitment and enrollment, the Informed Consent process, analysis of the study data, and the subsequent reporting to the sponsor
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts
- Disqualification of the researcher from all or part of the research project

Conclusion

Conflicts of interest can lead to bias and loss of objectivity so it is important that all participants in the research enterprise be vigilant and mindful of any relationships that appear to, or have a potential to compromise his or her interests. A conflict of interest implies only the potential for bias or wrongdoing, not a certainty. Intangible academic and tangible financial conflicts of interest will always exist. Devising new strategies manage, reduce, or eliminate conflicts of interest will be an ongoing challenge.

Case Studies

I. The Entrepreneurial Psychologist

John Cardoza, Ph.D., is an assistant professor in the Psychology Department at Westfield University. For five years he has been working on an important project on cognition in high school students. The work has shown great promise and Dr. Cardoza believes that he is on the threshold of developing a new algorithm to predict how well high school students will perform in the college environment. He is about to publish, but he still has some analyses to complete. He believes that his extensive manuscript will support his nomination for promotion to associate professor, a position he is eager to attain.

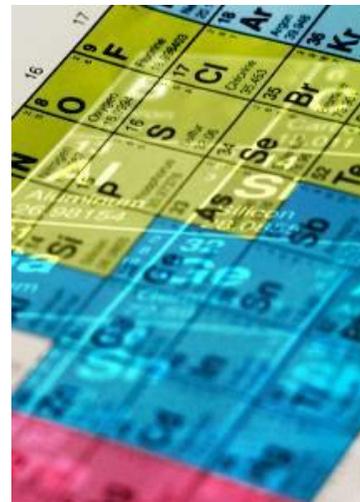


The editor of a major Psychology Journal has sent Dr. Cardoza a manuscript to review. It is written by a colleague in the same field and on the same topic. The findings described in this manuscript are disturbingly similar to his own. Dr. Cardoza wonders whether he should return the manuscript to the editor or try to review the manuscript as objectively as possible. Because he is an expert in this specialized area, he is undoubtedly the most knowledgeable reviewer for the manuscript. He is asked to complete the review of the manuscript within three weeks, and he realizes that he will not be able to complete his own paper within this period and get it sent off to the journal.

1. *Is there a problem with Dr. Cardoza reviewing his colleague's manuscript, given that he is probably the most qualified reviewer?*
2. *What potential conflicts of interest may Dr. Cardoza be experiencing?*
3. *Who could Dr. Cardoza disclose his concerns to, in this situation?*

II. The Conflicted Consultant

Mary Smith is a department administrator at Flat Plains College working in the Chemistry Department for twenty years. During that time, she has worked closely with and has developed a highly professional and trusting relationship with Professor Thomas. Three years ago, the College signed a research agreement with *ApeX Chemicals Inc.* At the end of the third year, *ApeX Chemicals Inc.* decided not to continue the sponsored project agreement and at the end of the third year, the agreement was terminated. Professor Thomas had other contacts at *Zeta Inc.*, and the College was able to execute a sponsored project agreement to fund the research for another three years. Professor Thomas, being very busy, told Mary that *Zeta Inc.* also wanted him to sign a consulting agreement. Because he trusted her implicitly, he wanted Mary to negotiate the personal consulting agreement for him. When Mary looked at the agreement she found that the statement of work was identical to the statement of work contained in the *Zeta's* sponsored project agreement with the College. While the sponsored project agreement signed by the College preserved intellectual property rights for the university, the consulting agreement would give all intellectual property rights to the *Zeta Inc.*



In addition, in the consulting agreement, Professor Thomas would agree to use his graduate students to perform the research at no cost to the company since this would be a "learning experience" for them and would give them exposure to valuable experience. Finally, Professor Thomas told Mary Smith that it would be very helpful to him if she would collect payments under the consulting contract and administer the funds through a private bank account he would establish. Mary felt uneasy but was not sure what was causing this gut reaction. She believed in doing the right thing, but she also felt that if she refused to help Professor Thomas, she was betraying their long-standing trust and professional relationship.

1. *Who are the interested parties?*
2. *What conflicts are present in this situation?*
3. *Should Mary have gotten this involved in the consulting arrangement?*
4. *What has Prof. Thomas done wrong?*
5. *What are the consequences?*
6. *What needs to be done to resolve the various problems?*
7. *What are the obligations?*

III. Janet's Suspicions

Professor Smith has made no secret of his consulting arrangement with *Apex Testing Inc.*, a company that conducts marketing research. He travels to Miami to meet with company representatives on many occasions. Sometimes he is in Miami several days at a time, and frequently visits *Apex Testing* two or three times per month. Janet Jones, his department secretary, makes his travel arrangements. Prof. Smith also makes no secret of the fact that the vacation he took to Paris this year and his new Porsche 911 were made possible by the money he made in his consulting activities with *Apex Testing Inc.*



Last week he submitted a proposal to the National Science Foundation (NSF) on work closely related to the work he has been doing for *Apex Testing*. As Janet was preparing the proposal packet, she noticed that he checked "no" next to all the questions on the Conflict of Interest Disclosure. She is aware that faculty are permitted to consult with external entities one day per week. She also wonders how Prof. Smith can answer "no" to questions about whether he has any significant financial interest with a company that could benefit from the research. She was very uncomfortable with this and decided to ask Prof. Smith about the Disclosure. He took offense and said "How dare you question my integrity! This is none of your business, so just do as you are told and take the proposal to OSP to get signed." Janet is concerned as to what is the appropriate action to take without being penalized. If she reports Prof. Smith, she might get fired.

1. *Could she prove that Prof. Smith really did anything wrong?*
2. *What if she reported the situation and she turned out to be wrong, or what if Professor Smith had a special arrangement that allows him to do so much consulting?*
3. *But then, what if she is right and doesn't report the situation?*

Resources

USC Institutional COI in Research:

<http://ooc.usc.edu/conflict-interest-research>

USC COI and Ethics:

<http://www.usc.edu/academe/acsen/Documents/Resolutions/conflictinterestbusiness.htm>

USC Code of Ethics:

http://policies.usc.edu/policies/USC_Code_of_Ethics_2004.pdf

USC Statement of Outside Interests Related to Research Form:

<http://dcg.usc.edu/Propprep/pdffiles/outer.pdf>

CITI Program:

www.citiprogram.org

NIH COI Guidelines:

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

NSF COI Guidelines:

<http://www.nsf.gov/od/ogc/ethics.jsp>

ORI Introduction to Responsible Conduct of Research (2007):

<http://ori.hhs.gov/documents/rcrintro.pdf>

USC Contacts

Office for the Protection of Research Subjects

3720 South Flower Street, Third Floor
Los Angeles, CA 90089-0706
Tel (213) 821-1154
Fax (213) 740-9299
E-mail: oprs@usc.edu
<https://oprs.usc.edu/>

Health Sciences Institutional Review Board

General Hospital, Suite 4700
1200 North State Street
Los Angeles, CA 90033
Tel (323) 223-2340
Fax (323) 224-8389
E-mail: irb@usc.edu
<https://oprs.usc.edu/hsirb/>

University Park Institutional Review Board

Credit Union Building (CUB), Suite 301
3720 S. Flower Street
Los Angeles, CA 90089
Tel (213) 821-5272
Fax (213) 821-5276
E-mail: upirb@usc.edu
<https://oprs.usc.edu/upirb/>

Office of Research

Credit Union Building, Suite 325
3720 S. Flower Street
University of Southern California
Los Angeles CA 90089-4019
Tel (213) 740-6709
Fax (213) 740-8919
E-mail: vice.president.research@usc.edu
<http://www.usc.edu/research/>

CITI Helpdesk

Tel (213) 821-5272
E-mail: citi@usc.edu
<https://oprs.usc.edu/education/citi/>

iStar Technical Help

Tel (323) 276-2238
E-mail: istar@usc.edu
Web: <http://istar-chla.usc.edu>

Office of Compliance

3500 Figueroa Street
University Gardens Building, Room 105
Los Angeles, CA 90089-8007
Tel: (323) 740-8258
Fax: (213) 740-9657
E-mail: complian@usc.edu
<http://www.usc.edu/admin/compliance/>

USC Stevens Institute for Innovation

3740 McClintock Ave. Hughes EEB 131
Los Angeles CA 90089
Tel: (213) 821-5000
Fax: (213) 821-5001
<http://stevens.usc.edu/>

Health Research Association (HRA)

1640 Marengo Street, 7th Floor
Los Angeles, CA 90033
Tel (323) 223-4091
Fax (323) 342-0947
Web: <http://www.health-research.org/>

IRB Student Mentor

Tel (213) 821-1154
E-mail: irbgara@usc.edu
<https://oprs.usc.edu/education/mentor/>

Office of Contracts and Grants-UP

Credit Union Building (CUB), Suite 303
3720 S. Flower Street
Los Angeles, CA 90089
Tel: (213) 740-7762
Fax: (213) 720-6070
<http://www.usc.edu/research/dcg/>

Office of Contracts and Grants-HSC

1540 Alcazar Street, CHP 100
Los Angeles, CA 90033-9002
Tel: (323) 442-2396
Fax: (323) 442-2835
<http://www.usc.edu/research/dcg/>