



Guidance and Procedure: Investigator Financial Conflict of Interest

(last updated October 16, 2014)

[Principles and Background](#)

[Investigator Responsibilities](#)

[Referral to and Coordination with the Conflict of Interest Committee \(CIRC\)](#)

[webIRB Application Procedures](#)

[Recommended Consent Form Language](#)

[References](#)

Principles and Background

Guiding Principles

The term “conflict of interest in research” refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research. A conflict of interest depends on the situation, and not on the actions or character of an individual investigator.

It is important that researchers involved in the conduct of human research do not have or appear to have a conflict of interest, including a financial interest, related to any of the studies in which they participate. The welfare and safety of the research participant is paramount. The fact that an investigator has or appears to have a conflict of interest in research does not preclude conduct of that research, but the interest must be disclosed and the conflict managed in a way that ensures that the welfare of subjects and the integrity of the data are not compromised by that interest.

Background

The increase in financial relationships between research institutions, investigators and research funders has led to calls for greater disclosure to human subjects of these relationships. Congress,¹ government agencies,² courts of law,³ and professional associations⁴ have all taken the position that, in order for research subjects to be able to give a consent that is fully informed, they should be advised of relevant financial interests of investigators and research institutions.

This guidance in conjunction with the information and requirements posted on [Conflict of Interest in Research](#) section of the UCLA Research Policy and Compliance website will help investigators comply with the DHHS guidance and the federal regulations, state laws, and University of California policies governing the disclosure and management of potential or actual financial interests in human research.

¹ Meier, Barry. (2008, Oct. 17). Senators Question Financial Ties Between Doctors and Stent Manufacturers. *The New York Times*

² OHRP, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*

³ Moore v. UC Regents, 793 P.2d 479 (Cal. 1990)

⁴ AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*, December 2001 ; *Protecting Subjects, Preserving Trust, Promoting Progress 11: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, October 2002

Investigator Responsibilities

Principal Investigators and their Key Personnel should review the Office of Research Administration Quick [“Frequently Asked Questions about UCLA’s COI Procedures for the Implementation for State of California and Federal Regulations.”](#) This provides an excellent discussion about financial conflicts of interest in research and the responsibilities of investigators with respect to their own financial interests as well as financial interests of the key personnel in their studies. Principal Investigators and Key Personnel (individuals who share responsibility for the design, conduct, or reporting of results of a sponsored project) are required to disclose financial interests when proposals for research are submitted.

When submitting an IRB application, the investigator and key personnel must also disclose financial interests. Based on that interest, the investigator should refer to the example statements that should be included in the consent form and include those that he or she believes are appropriate for the study.

Investigators must disclose to the IRB all existing financial interests in the research as a part of their initial IRB submission, continuing review submissions and at any time the investigators’ interest changes.

Referral to and Coordination with the UCLA Conflict of Interest Committee (CIRC)

Requirements for Investigator Financial Disclosure

Federal regulations, state laws, and University policies require that faculty members submit financial disclosure forms at the time that a proposal is submitted for funding. In those cases in which a financial interest and possible conflict of interest are disclosed, the laws provide for the review of each situation by an impartial review committee. At UCLA, that committee is the Conflict of Interest Review Committee (CIRC).

Charge of the CIRC

The UCLA CIRC reviews the personal financial interests reported by Investigators to determine whether those financial interests, and occasionally certain institutional interests, constitute conflicts of interest that might compromise, or potentially compromise, the objectivity of the work to be conducted. The Committee functions as an administrative board advisory to the Vice Chancellor for Research. Committee members are appointed by the Chancellor. The committee copies its recommendations to the PI, to the IRB, and to other appropriate individuals.

IMPORTANT NOTE: When a financial interest may affect the protection of human subjects, disclosure to potential human subjects and/or the public cannot be used as the sole method of management of the conflict of interest. The CIRC with the concurrence of the Executive Vice Chancellor will determine the appropriate management strategy for the research. For example, the CIRC and/or the IRB might recommend or require a limited role of researchers with certain financial interests to recruit or consent subjects or to analyze data related to the study.

Coordination between the CIRC and the IRB

The two oversight committees coordinate their reviews with each other and the PI to make sure that the study incorporates the recommendations to manage any potential conflicts of interest. The IRB will notify CIRC if an investigator discloses a financial interest in webIRB and CIRC will notify the IRB if it finds directly from the researcher, the Office of Contracts and Grants or other sources that a researcher has a financial conflict of interest. Approvals are coordinated.

IMPORTANT NOTE: *The IRB has the final authority to determine whether the research with the financial interest and the management plan, if any, allow the research to be approved.*

webIRB Application Procedures

The webIRB application includes a section called “**Conflict of Interest**” which asks: “Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?”

IMPORTANT NOTES:

- **The definition of “key personnel” that is currently in the webIRB** application is: “Key personnel include other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved with handling private information related to study participants during the course of a research project.
- **This definition of key personnel is more inclusive than the NIH definition because it also includes people who participate in the conduct of research who may not contribute substantively to the development or execution of the project...**”
- **UCLA Procedure 925.3** says that disclosures must be made by the PI and other “Investigators”. Investigators are defined **as “individuals who share responsibility with the PI for the design, conduct or reporting of the research.”**

If the answer is affirmative,

- a series of questions will follow about the type of interest;
- the IRB members will review the responses and assure that the consent form includes appropriate wording and ask any other management strategies they believe are appropriate (i.e., ask that the investigator not recruit or consent subjects or not be involved in the data analysis);
- the CIRC will be notified that an investigator has answered in the affirmative, review the relevant sections of the webIRB application, ask for additional information, and review any additional information as needed before making its final recommendations to the Vice Chancellor.

Recommended Consent Form Language

The IRB will ask that the consent form include information about the sources of funding for the study, investigator conflicts of interest, institutional conflicts of interest, and how to find out additional information.

FUNDING SOURCE

In the section Purpose section of the consent form, that is, “Why is this study being done?” the IRB asks that the funding source(s) of the study or sponsors providing study drugs or equipment for the study be stated. If the study is not being funded by an external agency, then the internal funding source, i.e., Department funds, personal funds, should be identified.

Example wording to identify the study sponsor: This study is being funded by the National Institutes of Health (NIH) [or *Industry Sponsor* or *Private Foundation*].

Example wording to identify the provider of the study drug if different than the sponsor: *Commercial company name*, the manufacturer of the investigational drug being used in this study, is providing the study drug [or *device* or *assay*] at no cost [or *at cost*] to the researcher or research participant.

DISCLOSURE OF THE NATURE OF ANY FINANCIAL OR PROPRIETARY INTERESTS

In a section of the consent form entitled “Researcher Financial Interests in this Study” investigators must also disclose the nature of any financial or proprietary interests. The consent form should identify the researchers or research staff by name and by their role in the study.

Example of wording to indicate for an interest in an entity or the product:

Dr. Jane Doe, a researcher on the study team, has a financial interest in [*name of company*],

- the company paying for this study.
- the company that will manufacture the study drug
- the company that will sell the drug, *and/or*
- the company conducting part of this study.

Example of wording if the interest is other than a financial interest in an entity, e.g., in the product being tested: Dr. John Smith, the principal investigator for this study, has a financial interest in the [*product, drug, device, name of company*], being studied.

Example of wording to describe the interest:

- [*Name of company and relevance of company to study, e.g., sponsor*] is paying Dr. Cohen [*describe payment, e.g., consulting fee, salary*].
- Dr. Cohen is being paid to be a scientific advisor to [*name of company, relevance of company to study*].
- Dr. Cohen is an unpaid member of the Scientific Advisory Board of [*name of company, relevance of company to study*].
- Dr. Cohen is on the board of [*name of company, relevance of company to the study*].
- Dr. Cohen is the [*president, chief executive officer*] of [*name of company, relevance of company to study*].

Example of wording to describe significant stock ownership in a publicly traded company, stock ownership in a non-publicly traded company, and for stock options:

- Dr. Rodriguez owns stock in [*name of company, relevance of company to study*].
- Dr. Rodriguez is a [*founder or majority or minority shareholder*] of [*name of company, relevance of company to study*].
- Dr. Rodriguez has a stock option from [*name of company, relevance of company to study*] and may get income in the future.

Example wording for the inventor:

- Dr. Chan invented the [*drug, device*] being studied and may benefit financially if it is marketed.
- *If possible, elaborate on the information provided, e.g.,* The consulting income Dr. Chan receives is in addition to her salary from the University of California.

DISCLOSURE OF ANY LICENSING OR EQUITY INTERESTS OF THE UNIVERSITY

Information concerning licensing agreements and equity interests is available from the Operational Tools database maintained by the UCOP Innovation Alliances Services Office. The CIRB may also identify this information when it reviews a particular study.

If the study includes researcher and university financial interests, ***a section of the consent form entitled “Researcher and University Financial Interests in this Study”*** should include the researcher financial interests described above and any licensing or equity interests of the University.

Example wording for University interests:

- The University of California has a financial interest in this study.
- The University has granted a license to a private company to develop the [*drug, device*] being tested in this study. If the [*drug, device*] proves to be safe and effective, the University could financially benefit from sales of the [*drug, device*].
- The University owns stock in a private company, which is the manufacturer of the [*drug,*

device] being tested. This means that the value of the University's stock could go up or down depending on the results of the study.

EXPLAIN WHY THESE DISCLOSURES ARE BEING MADE AND WHERE A PARTICIPANT COULD RECEIVE ADDITIONAL INFORMATION

Example wording: This disclosure is [these disclosures are] made so that you can decide if this relationship [these relationships] affect your willingness to participate in this study. If you have questions, tell the study coordinator and she [he] will put you in touch with someone to talk to.

EXAMPLES OF DISCLOSURE PARAGRAPHS

- Dr. Jane Doe, a researcher on the study team, has a financial interest in XYZ, Inc., the company paying for this study. Dr. Doe is a consultant for XYZ, Inc. The consulting fee Dr. Doe receives is in addition to her salary from the University of California.
- The University of California also has a financial interest in this study. The University has granted a license to a private company to develop the drug being studied. In addition, the University owns stock in this private company. This means that the value of the University's stock could go up or down depending on the results of the study.
- If you have questions, tell the study coordinator and they will put you in touch with someone to talk to.

References

- [Financial Interests Disclosure Form: Research Sponsored by a Government Agency](#)
- [Financial Interests Disclosure Form: Sponsor of the Research\(For-Profit or Not-for-Profit\)](#)
- [UCLA Conflict of Interest in Research](#) website
- [UC Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest](#)
- [UCOP RPAC Operating Guidance Memo 11-04: Financial Interest Disclosure in the Research Consent Form](#) (June 1, 2011)
- [UCOP RPAC Operating Guidance Memo 11-05: Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research](#) (June 1, 2011)