Published on *UCSF Institutional Review Board* (https://irb.ucsf.edu)

Conflicts of Interest (COI) in Research

What Is a COI and How Is It Managed?

The term ?conflict of interest (COI) 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 COI depends on the situation and not on the actions or character of an individual investigator.

It is important that researchers involved in human research do not have or appear to have a COI ?including a financial interest?related to any of the studies in which they participate.

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. When a financial interest and possible COI is disclosed, the case is reviewed by an independent review committee, the Chancellor?s Conflict of Interest Advisory Committee (COIAC) [1].

Charge of the COIAC

The COIAC reviews a potential financial COI disclosure and makes recommendations to the Chancellor and/or the Chancellor's designee for acceptance, acceptance with conditions, or disapproval of the gift, grant or contract. The COIAC must review and approve conflicts before funding can be accepted and the research can begin.

The COIAC copies its recommendations to the PI, the IRB and other appropriate individuals. The COIAC may recommend, for example, that the financial interests be disclosed in the consent form.

Note: When a COI 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 COI. The COIAC with the concurrence of the Chancellor and/or the Chancellor's designee will determine the appropriate management strategy for the research.

The COIAC and IRB will coordinate with the PI to ensure the study incorporates the COIAC's recommendations to manage a potential COI.

IRB Application Procedures

The IRB Application asks you to respond ?yes? or ?no? to the following statement: "Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests [1] related to this study?" Additional information on financial interests is available on the COIAC website. [1]

If the answer is "yes," take the following two actions:

- Keep all financial interest disclosures current with the COIAC office [1]. The COIAC Office may contact you for additional information.
- Briefly describe this financial interest in the consent form. See the sample wording below.

Recommended Consent Form Language

Informed consent documents for UC research projects require that ?(a) a physician must disclose personal interests unrelated to the patient?s health, whether research or economic, that may affect the physician?s professional judgment; and (b) a physician?s failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of confidentiality.?

Briefly describe the following info in the "Why is this study being done?" or "What are the costs?" section of the consent form:

- **Funder:** Disclose which agencies or institutions, cooperative groups, foundations or industry sponsors are funding the research or providing study drugs or equipment for the study. If the study is not being funded by an external agency, then identify the internal funding source (i.e., department funds, personal funds).
- **Financial or proprietary interests:** Also disclose the nature of any financial or proprietary interests, though this disclosure can be in general terms.

Recommended consent form wording by situation

Situation	Recommended Wording
To identify the funder	The National Institutes of Health (NIH) [or industry sponsor or private foundation] pays for the conduct of this study, including part of Dr. Smith?s and Dr. Chang?s salary [if the latter is the situation].
Drug, device or assay provided by the sponsor	[*Company name*], the manufacturer of the investigational drug [*or device or assay]* 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.
Researcher is a Scientific Advisory Board member	Dr. Smith is an unpaid member of the Scientific Advisory Board of the company that is sponsoring this study. Dr. Smith is a paid [or an unpaid] member of the Scientific Advisory Board of a related company [or foundation] [or a company or foundation that is performing research in the same area as this study].
Researcher has stock in the company	Dr. Smith has stock in a company that is performing research in the same area as this study.
Researcher is listed on a patent	Dr. Smith developed the Y device that is used in this study and he has a personal interest in the device. Dr. Cohen and the University of California may benefit financially if the device does what they hope it will do.
Researcher received honoraria or travel reimbursement	Dr. Smith has received an honoraria [or travel reimbursement] during the past 12 months from the study sponsor.

You may also add: This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.

Avoidance of IRB Member or Consultant COI

It is important that the members or expert consultants of the IRB do not have or appear to have a COI related to any of the studies in which they participate in the review process.

An IRB member is provided guidelines [2] for considering the actual or potential COI, and also determining whether a particular role or relationship could affect his or her objectivity before reviewing, participating in the panel discussion or deliberation, and voting on a protocol. Members who have a COI on a particular protocol are required to recuse themselves from reviewing or voting on a particular protocol. Procedures are in place to make sure that this occurs at every meeting and for the review of every study.

Page last updated:
Apr 10, 2017

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