

Policy Number: 63

Title: Investigator Financial Interests and Conflicts of Interest

Date of Last Revision: July 5, 2007

For the purposes of this policy only, the term, “investigator,” includes all investigators and key research personnel¹.

I. Investigator Conflict of Interest – Overview

- A. An investigator has a conflict of interest in a research study when s/he has interests in the outcome of the research that might compromise the integrity of the research.
- B. A researcher has an ethical responsibility to disclose a possible conflict of interest or a possible appearance of a conflict of interest to potential research subjects as part of the informed consent process.
- C. As outlined in the Executive Vice Chancellor’s memorandum dated April 20, 1999 [see attached], investigators must disclose possible conflicts of interest in research in the informed consent document when (a) an investigator is responsible for the healthcare of the subjects and/or (b) an investigator has financial interest in the sponsor of the study.
- D. UCLA has organization-wide mechanisms in place to determine whether a financial conflict of interest exists and, if so, whether action must be taken to eliminate, reduce or manage the conflict before the contract, grant or gift supporting the research may be accepted. Please refer to organizational policies and procedures regarding conflict of interest for details. (e.g., [UCLA Policy 150: Conflict of Interest](#) and [UCLA Policy 925: Financial Conflicts of Interest in Research](#).)

II. Financial Interests

- A. An interest may be in an article being tested or in an entity related to the research. A related entity may include the sponsor or another entity that would reasonably appear to be affected by the research, such as a Contract Research Organization or the manufacturer of the test article.

¹ Key personnel are self-identified based on institutional policy.

- B. An individual's interests also include interests held by a spouse, registered domestic partner or dependent child.
- C. Financial interests may include, but are not limited to, the following within the prior 12 months or expected within the next 12 months:
 - 1. A position as director, officer, partner, trustee, employee of, or any other position of management in a related entity
 - 2. Income from a related entity, such as salaries and wages, consulting income, honoraria for services performed, per diem, reimbursement for expenses, rental income, dividends and interest, and proceeds from sales
 - 3. Investments including stocks, bonds, warrants, and options in a related entity, including those held in margin or brokerage accounts, or an ownership interest in a related entity
 - 4. Gift(s) totaling at least \$50 or loan(s) from a related entity
 - 5. An intellectual property interest (including royalty or other income) on a patent, patent application or copyright related to the research, including intellectual property assigned or licensed to The Regents of the University of California
- D. A sponsor's support for the project (such as salary support paid by the University from the grant or the reimbursement of study-specific travel costs) is not considered a financial interest.
- E. 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.
- F. The IRB (or IRB Chair/designee) will evaluate whether a disclosed interest needs to be:
 - 1. included in the informed consent document;
 - 2. otherwise managed, such as to address particular potential for coercion; and/or,
 - 3. referred to the Conflict of Interest Review Committee (see Section III below).

III. Conflict of Interest Review Committee [CIRC]

- A. The Conflict of Interest Review Committee (CIRC) is an independent faculty body, advisory to the Vice Chancellor for Research, that reviews investigator financial interests to determine whether such interests present real or perceived conflicts of interest under applicable laws and regulations.

- B. CIRC and the IRBs independently collect information regarding financial interests. As a safeguard, the IRB forwards to CIRC all information regarding interests that appear to cross the University's thresholds for review by CIRC. Such thresholds are defined in institutional policies.
 - 1. As CIRC has expertise in the review and management of conflicts of interest, the IRBs may also seek the advice of CIRC regarding matters that do not cross the University's thresholds for review by CIRC.
- C. Upon completion of its review, CIRC forwards its recommendations to the Vice Chancellor for Research who makes the final decision about acceptance of the award..
- D. CIRC and the Vice Chancellor for Research notify the IRBs of final determinations, including recommendations regarding management of the investigator's economic interest in the sponsor.
- E. Determinations and management plans forwarded by CIRC and the Vice Chancellor for Research must be reviewed by the IRB (or by the IRB Chair/designee). The IRB has final authority in approving research based on such determinations and management plans. The IRB may require changes to the management plans in order to better protect human subjects.
 - 1. When a conflict of interest is being reviewed by CIRC for the Principal Investigator, IRB approval of the research as a whole is contingent upon IRB's receipt and acceptance of CIRC determinations and the Principal Investigator's implementation of any actions recommended by CIRC.
 - 2. When a conflict of interest is being reviewed by CIRC for a co-investigator, the co-investigator may not participate in the research until IRB has received and accepted CIRC determinations and the Principal Investigator and co-investigator have implemented any actions recommended by CIRC.

IV. Health Care Provider/Investigator Conflict of Interest

- A. As a part of the application to involve human subjects in research, the investigator must indicate whether any members of the research team are also the subjects' treating physicians/clinicians.
- B. If an investigator may be directly involved in potential subjects' health care, precautions must be undertaken to avoid the appearance of coercion or conflict of interest in the recruitment process. Please refer to policies and procedures regarding recruitment methods and tools for details.

- C. Investigators must describe such conflict of interest in the informed consent document. The following standard section should be inserted into the consent form after the introductory section:

Disclosure Statement

If your doctor is involved in this research, he or she is interested both in your health and in the success of this research. At any time before and during the research, you may ask for a second opinion about your care from another doctor that is not associated with this research. You do not have to participate in any research offered by your doctor.

V. Non-UCLA Investigator Conflict of Interest Evaluation

- A. When UCLA collaborates with one or more sites, and the non-UCLA sites have a designated IRB which reviews and approves the protocol, the non-UCLA sites are responsible for the evaluation and management of conflicts of interest of their investigators.
- B. When UCLA collaborates with one or more sites, and the UCLA IRB is the designated IRB for any non-UCLA sites, the UCLA IRB will evaluate and manage the conflicts of interest of the non-UCLA investigators.

Regulations:

42 CFR 50 – Subpart F

References:

California Supreme Court Decision in *Moore v. The Regents of the University of California*, 51 Cal.3d 120; 793 P.2d 479; 271 Cal Rptr. 146.
<http://www.courtinfo.ca.gov/opinions/continue.htm>

Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection” [<http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>], May 5, 2004.

Attachments:

- OPRS-3 UCLA OPRS Human Research News, "Disclosure of Possible Conflict of Interest to Human Research Subjects," [http://www.oprs.ucla.edu/human/news/item?item_id=119763], April 20, 1999.
- OPRS-89 UCLA OPRS Human Research News, "Simplified Financial Disclosure Requirements," [http://oprs.ucla.edu/human/news/item?item_id=246705], February 23, 2007

- UCLA-1 UCLA Policy 150: Conflict of Interest
[http://www.adminvc.ucla.edu/appm/public/app_0150_0.html]
- UCLA-6 UCLA Policy 925: Financial Conflicts of Interest in Research
[<http://www.adminvc.ucla.edu/appm/public/925.htm>]
- UCLA-7 UCLA Conflict of Interest in Research Frequently Asked Questions
[http://www.research.ucla.edu/researchpol/documents/faq_coi.pdf]
- UC-8 University of California Policy: General University Policy Regarding Academic Appointees -- Disclosure of Financial Interest in Private Sponsors of Research
[<http://www.ucop.edu/acadadv/acadpers/apm/apm-028.pdf>] (April 1984: APM-028).
- UC-12 University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects,
[<http://www.ucop.edu/research/policies/disclosure.html>], October 15, 1997.