



Policy Title: Individual Conflict of Interest in Research & COIC

Category: Conflict of Interest

Policy Number: 112

Sponsor: Chief Compliance Counsel

Effective Date: January 7, 2009

INTRODUCTION AND PURPOSE. As key participants in the discovery of knowledge through research, the University and the individual investigators recognize the shared obligations to protect the rights and welfare of human subjects involved in that research, promote the ethical care and use of animals involved in that research, and protect the integrity of the data generated by that research. The ability to fulfill those obligations is compromised when bias or the appearance of bias is introduced through a personal interest held by the investigator. This policy is designed to ensure the design, conduct, and reporting of research conducted under auspices of the University is not biased and does not appear to be biased by a personal interest held by an investigator in that research.

CANCELLATION. COI Policy 112 entitled “Employed Faculty - Research” dated May 31, 2006 is cancelled.

SCOPE AND APPLICABILITY. This applies to all employed faculty members, to all investigators (as that term is defined in this policy), and to members of the Conflict of Interest Committee. The scope of this policy is limited to personal interests held by investigators as they relate to research projects.

POLICY STATEMENTS.

The design, conduct, and reporting of research conducted under auspices of the University must not be biased or appear to be biased by a personal interest held by an investigator.

An investigator who has a conflicting interest relating to a particular research project may *not* participate in that research project *unless* that investigator complies with a specific plan approved by the Conflict of Interest Committee (COIC).

The COIC has the authority and responsibility to review proposed plans to manage an individual conflict of interest in research and may approve such a plan only when the COIC determines that such plan is effectively designed to:

- * protect the rights and welfare of human subjects involved in that research (if any),
- * promote the ethical care and use of animals involved in that research (if any), and
- * protect the integrity of the data generated by that research data.

Heightened scrutiny is warranted for human subject research that is affected by a significant conflict of interest.

The University’s IACUC and IRB are *not* required to accept a plan that was approved by the COIC. The IACUC or IRB may require that the management plan contain additional elements as those other bodies fulfill their independent oversight responsibilities.

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DEFINITIONS.

Conflicting interest. A *conflicting interest*, for purposes of this policy, is when the investigator has any of the *personal interests* described in subparagraphs 1.a through 1.e of the Procedures section of this Policy.

Personal interest. A *personal interest* (sometimes termed individual interest) is any interest held by the individual that is not associated with employment or affiliation with the University (*e.g.* salary from this University is not a personal interest). Although the scope of the term is vast, the most common types of personal interests fit into three categories: financial, familial, and organizational.

1. A financial interest is the receipt or expectation of receiving a thing of monetary value (*e.g.* stock, patent, partnership, gift, income, reimbursements, and honoraria).
2. A familial interest is an existing or expected relationship with a particular person by blood, marriage, or adoption (or substantially similar relationship).
3. An organizational interest is a current, recent, or expected status as member, employee, officer, director, trustee, consultant, or agent of an entity.

Significant Conflicting Interest. A *significant conflicting interest* is a *conflicting interest* that meets the following thresholds (intended to reflect relevant PHS regulations and best practices thresholds):

1. ownership, equity, or entitlements to equity in a non-publicly traded entity;
2. ownership, equity, or entitlements to equity in excess of \$10,000 in value or more than 5% ownership in a publicly traded entity (*e.g.* stock or options but does not include a publicly traded mutual fund);
3. intellectual property (*e.g.* patent or copyright);
4. remuneration for service, expense, or other purpose (*e.g.* consulting fees, honoraria, or travel reimbursements) from a single entity that totals \$10,000 or more in a 12-month period;
5. serve as officer, member of a board/committee, or employee of an entity; or
6. loan or debt of over \$10,000 to a single entity.

Investigator. For purposes of this policy, investigator means the principal investigator and any other person who shares responsibility for the design, conduct, or reporting of research.

Research conducted under the auspices of the University. For purposes of this policy, research conducted under the auspices of the University means projects where an investigator conducts research activities as part of his or her role as a faculty member of the University. As such, the University is considered to be engaged in the research through the activities of the particular investigator.

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PROCEDURES.

1. Formal Disclosure. Each employed faculty member shall, on an annual basis, complete and submit a conflict of interest disclosure report. The Office of Compliance will create a form for such purpose that will solicit a disclosure of and detailed information related to the following:

a. any personal interest in the experimental item of any research project in which the faculty member is or expects to be involved as an investigator;

b. any personal interest that would reasonably appear to be affected by the results of any research project in which the faculty member is or expects to be involved as an investigator;

c. any personal interest in/from the external sponsor of any research project in which the faculty member is or expects to be involved as an investigator;

d. any personal interest in/from any other entity whose financial interests would reasonably appear to be affected by any research project in which the faculty member is or expects to be involved as an investigator; and

e. any other personal interest that creates an actual or apparent bias or improper influence upon the faculty member's judgment relating to any research project in which the faculty member is or expects to be involved as an investigator.

2. Routing of COI Disclosure Report. All COI disclosure reports will be forwarded to the Office of Compliance with an intermediate routing as required by the cognizant Dean. If *no* conflicting interests were disclosed, no further review is required. If *any* conflicting interest was disclosed, the Office of Compliance will gather further information and assist the Chair of the COIC present the matter to the COIC for review.

3. COIC - Composition. The COIC consists of five or more members, appointed in writing by the President, for a term of three years, and will normally include:

a. faculty who is currently or was within the past 12 months a member of the University's Institutional Review Board (IRB);

b. faculty who is currently or was within the past 12 months a member of the University's Institutional Animal Care and Use Committee (IACUC);

c. faculty with experience in basic science research;

d. faculty with experience in clinical research; and

e. one person not affiliated (and not related to a person affiliated) with the University.

4. COIC - Chair. The Chair of the COIC is appointed by the President. The Chair calls for and schedules meetings, controls the meeting agenda, and signs documents on behalf of the COIC.

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5. COIC - Quorum and Voting. The COIC may act only when a quorum exists. A quorum exists when at least three current members are present and are qualified to participate. Qualified to participate means the member does not have a conflicting interest regarding the matter under review. The COIC acts as a body pursuant to a majority vote of the quorum. All members are voting members. A member must be present and qualified to participate to vote; voting by proxy is not permitted.

6. COIC - Review and Determination. The COIC will, based on an assessment of the all of the relevant factors listed in paragraph 7 of this policy, make one of the following determinations:

a. No Conflict of Interest. The COIC may determine that there is no conflicting interest only when the COIC is convinced that the investigator does not have any of the personal interests described in subparagraphs 1.a through 1.e of this policy.

Note: During the disclosure phase, investigators are advised to err on the side of disclosure when there is doubt. Accordingly, the COIC should anticipate there may be instances in which the COIC will, after appropriate assessment, determine that there is no conflict of interest.

b. Approve an Effective Management Plan. The COIC may approve a particular plan (and allow the investigator to participate consistent with that plan) only when the COIC, after assessing the relevant factors described in paragraph 7 of this policy, is convinced that the plan, in its entirety, effectively manages the conflicting interest. This means:

(1) The COIC is convinced that the plan is designed to

(a) protect the rights and welfare of human subjects involved in that research (if any) with specific attention given to the affected investigator's involvement in:

- (i) the human subject recruitment and selection,
- (ii) the interaction or intervention with human subjects, and
- (iii) the monitoring and adverse event reporting;

(b) promote the ethical care and use of animals involved in that research (if any), with specific attention given to the affected investigator's involvement in the procedures conducted on the animal; and

(c) protect the integrity of the data generated by that research with specific attention given to the affected investigator's involvement in:

- (i) data collection and analysis, and
- (ii) publication and authorship.

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- (2) The plan includes a requirement for the investigator:
- (a) to disclose the existence and general nature of the conflicting interest:
 - (i) to the human subjects involved in the research (if any),
 - (ii) to the sponsors or funders of the research (if any),
 - (iii) to all members of the research team (including students, volunteers, and trainees),
 - (iv) to the editors of any publication to which a manuscript is submitted concerning the research, and
 - (v) within any substantive communication of the research results.
 - (b) to state that further details about the conflict may be obtained from the investigator (who, then, must make further disclosure upon request).
- (3) For human subject research that is affected by a significant conflict of interest, the COIC determines it has clear and convincing evidence that:
- (a) there are compelling circumstances warranting the involvement of the affected investigator and
 - (b) the plan limits the involvement of the affected investigator to a minimum as indicated by those compelling circumstances.

Note: Management plans should be proposed by the investigator and provide sufficient detail to allow COIC review. These plans may include elements such as disclosures, oversight, redundancies, reduction of investigator involvement and/or reduction of the investigator's conflicting interest.

c. Non-Participation. The COIC must determine that the individual is not permitted to participate in the research project unless the criteria of paragraph 6.a or 6.b of this policy are fulfilled. Even when a management plan is proposed, the COIC may decline to approve that plan (*e.g. when the particular personal interest involved is such that no plan would be perceived to be effective or that the particular proposal is deficient in some manner and the COIC declines, for whatever reason, to modify the plan itself*).

7. COIC - Factors to Consider During Review. The COIC will consider:

- a. the specifics of the research activities, including the involvement of the affected investigator;
- b. the nature and specifics of the conflicting interest, including how the conflicting interest might be affected by the research results;
- c. the potential adverse impact if the research were influenced by the conflicting interest;
- d. the appearance to a reasonable person in the public whether the University is acting in accordance with ethical principles;

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e. the appearance to a reasonable professional in the scientific community of the research regarding its objectivity and data integrity;

f. any unique circumstances associated with the investigator (as contrasted with, for example, the availability of a qualified and willing alternate investigator who does not have a conflicting interest); and

g. the effectiveness of the elements in the proposed management plan to protect the rights and welfare of human subjects involved in that research (if any), promote the ethical care and use of animals involved in that research (if any), and protect the integrity of the data generated by that research data.

8. COIC - Advisors and Consultants. The COIC may seek the assistance of others in fulfilling its functions, including persons with knowledge of the specific facts and persons with specific subject-matter expertise. The Chief Compliance Counsel will provide advice and consultation regarding general conflict-of-interest concepts.

9. COIC - Communicating Determinations. The Chair of the COIC will sign correspondence on behalf of the COIC reflecting the COIC determinations and forward that correspondence to the affected investigator.

10. COIC - Administrative Support, Records, and Confidentiality of Information. The Office of Compliance will provide administrative support to the COIC and retain case files for a period of three years. Information that relates to a particular individual is deemed confidential and may be disclosed upon the consent of the individual, within the University on a need-to-know basis (*e.g.* the IRB, IACUC, and/or Office of Sponsored Research), or as otherwise provided by law.

POINT OF CONTACT. Office of Compliance (847) 578-8308