Policy on Researcher Financial Conflicts of Interest

Effective date: 9/20/2019

I. Background
Principal Investigators (PI) and key research personnel must report significant financial interests when applying for IRB review or exempt determination. The Conflict of Interest Committee shall review potential conflicts of interests and determine actions necessary, if any, to protect the rights and welfare of human subjects.

II. Definitions
a. Key research personnel: individuals responsible for the design, conduct, or reporting of the results of a study, which may be faculty, staff, or students.

III. Significant Financial Interests
a. Whether a financial interest is considered “significant” varies depending whether the study is funded, and if so, by sponsor, as outlined below:
   i. Studies with no external funding: In cases where an external entity does not contribute monetary support, but contributes something else of value – for example, software, materials, etc. – the following interests in that entity must be disclosed, whether held by anyone considered key research personnel (see above definition) or by their spouse/partner/dependent children:
      1. Income received from a publicly traded entity during the 12 months prior to disclosure which, when combined with the value of any equity interest you hold in the entity, exceeds $5,000.
      2. Income received from a non-publicly traded entity during the 12 months prior to disclosure that exceeds $5,000 OR any equity interest you hold in that entity.
      3. Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant)
      4. Rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed
   ii. Studies sponsored by a non-governmental entity (unless exempt, see COI website for more information): The following interests in the funding entity must be disclosed, whether held by the PI or their spouse/partner/dependent children:
      1. Income of $500 or more within the 12 months prior to the date that the award is made. Income (see full definition in 700U Form) includes any salary, wage, advance, dividend, interest,
Institutional Review Board

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2. Loan balances totaling $500 or more.
3. Gifts with a fair market value of $50 or more. A gift is anything of value for which you have not provided equal or greater consideration to the donor. Multiple gifts totaling $50 or more must be reported.
4. Investment totaling $2,000 or more.
5. A position of director, officer, employee, partner, trustee, consultant or management, whether paid or unpaid.
6. Travel advances and reimbursements totaling $50 or more if you did not provide services which were equal to or greater in value than the payments received; or totaling $500 or more if you provided services which were equal to or greater in value than the payments received. (Travel payments from your employer in the normal course of your employment excluded.)

iii. NSF sponsored research: The following interests must be disclosed, whether held by anyone considered key research personnel (see above definition) or their spouse/partner/dependent children, if the interest would reasonably appear to be affected by the research (or educational activities) funded or proposed for funding, or the interest is in entities whose financial interests would reasonably appear to be affected by such activities:

1. Outside income exceeding $10,000 over the preceding twelve months or anticipated during the forthcoming twelve months. Income includes salary, consultant payments, honoraria, royalty payments, dividends, loan, or any other payments or consideration with value, including payments made to the University Health Sciences Compensation Plan.
2. Equity in the form of stock, stock options, real estate, loan to, or any other investment or ownership interest exceeding $10,000 (current market value) or a 5% or greater ownership interest.
3. A management position – e.g., director, officer, employee, partner, or trustee, consultant – with the interested entity, whether paid or unpaid.
4. An intellectual property interest – e.g., a patent (actual, planned, or applied for) or a copyright for software assigned or to be assigned to a party other than the Regents.

iv. PHS sponsored research or sponsors who follow PHS policy: The following interests must be disclosed, whether held by anyone considered key research personnel (see above definition) or their
spouse/partner/dependent children, if the entity is related to the interested person’s UCSC institutional responsibilities:

1. Income received from a publicly traded entity during the 12 months prior to disclosure which, when combined with the value of any equity interest you hold in the entity, exceeds $5,000.
2. Income received from a non-publicly traded entity during the 12 months prior to disclosure that exceeds $5,000 OR any equity interest you hold in that entity.
3. Income received from an entity, other than UC, for intellectual property rights and interests during the 12 months prior to disclosure that exceeds $5,000. This could include royalties for books, or license fees for software or technology you may have invented before you came to UCSC.
4. Travel paid for or reimbursed by a for-profit or non-profit entity, including professional organizations and foreign universities, that exceeds $5,000 per entity per 12-month period.

IV. Principal Investigator Responsibilities

a. The PI must disclose all financial interests that are significant as defined above, regardless of whether the study is funded. ORCA will request more information as needed from the relevant parties and either make a determination of Not-A-Conflict or, if required, forward to the COI committee (COIC) for further review.

b. Significant financial interests must be reported on the IRB Financial Interest Disclosure Form on all of the following occasions:
   i. During initial submission;
   ii. When adding research personnel;
   iii. At continuing review; and
   iv. Within 30 days of any change/new significant financial interest.

c. If applicable, researchers must affirm they will adhere to the COIC’s management plan and/or recommended safeguards and any additional concerns the IRB may have regarding the interest.

V. ORCA Responsibilities

a. ORCA will contact any personnel with a disclosed interest for more information as needed.
b. ORCA will either make an administrative determination of Not-A-Conflict or, if required, forward to the COIC for further review. ORCA also provides the scope of work to the COIC.
c. ORCA will forward COIC management plan/safeguards to IO for approval.
d. ORCA will get personnel agreement to any management plan or safeguard.
e. ORCA will provide any COI management plans or safeguards to expedited reviewers or the full IRB, as applicable.

VI. IRB Responsibilities
a. The IRB may decide to approve the study contingent on adherence to the COIC management plan/safeguards.
b. The IRB may require that the COIC’s management plan/safeguards are implemented exactly as written, or it may choose to revise as necessary in order to protect the rights and wellbeing of subjects.

VII. COI Review
a. ORCA and/or the COIC will review significant financial interests related to human subjects research to make sure that there is sufficient separation of University and private interests, that the proposed research is consistent with the University’s interests, that the teaching and research environment remains open, that freedom to publish and to disseminate research results is preserved, that the University's intellectual property rights are protected, and that the University's facilities and resources are used appropriately and that the University receives proper compensation for their use.
b. The COIC must determine whether the interest will adversely affect the integrity of the research and/or rights and wellbeing of subjects and, if so, develop actions to safeguard against risks, or else recommend the reduction or elimination of interests.
c. The COIC may recommend safeguards or a management plan for approval.

VIII. References
a. UC Irvine Policy Investigator and Research Personnel Conflicts of Interest
b. UC Office of the President Policy on Disclosure of Financial Interest in Private Sponsors of Research (APM-028)
c. UC Office of the President University Guidelines for Disclosure and Review of Principal Investigator's Financial Interest in Private Sponsors of Research