Research
Conflict of Interest
Navigating the system
What is a financial interest?

- Anything of economic value, including a fiduciary relationship with an outside entity (profit or non-profit.)
What is a conflict of interest?

- In very broad terms, a conflict of interest is a situation in which an investigator's financial interest(s) or obligation(s) (real or perceived, paid or unpaid) have the potential to bias a research project.
What is a financial conflict of interest in research?

- A financial conflict of interest in research is a situation in which an objective layperson might perceive that an investigator’s financial relationships may bias his or her work.
Is a financial interest automatically a conflict of interest?
Not Necessarily ...

- Almost all *disclosed* financial interests and resulting actual conflicts of interest can be reduced, managed, or eliminated so that the research support can be accepted.

- THE KEY IS DISCLOSURE AND REVIEW
Policies, guidance and review

- Policies relative to conflict of interest are found on the COI Committee website at:
  http://researchcoi.berkeley.edu

- Website has links to Federal, State, University and campus implementations, guidance, case studies, FAQ’s, etc.
Conflict of Interest
http://researchcoi.berkeley.edu
Conflict of Interest

Policy and Review

UC and UC Berkeley Policies and Guidance

Frequently Asked Questions about UC Berkeley's Conflict of Interest Policy and Procedures

Quick Conflict of Interest Filing Guide

Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest (UCOP Business and Finance Bulletin G-39)

Guide to Consulting for Faculty and Academic Employees: campus memo, Guide (UCB)

Participation in Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs (UCB)

Conflict of Interest Review of Directors of Joint Research Centers (UCB)

Conflict of Interest/Conflict of Commitment Cases (UCB)

Conflict of Commitment and Outside Activities of Faculty Members (UCOP APM - 025) (PDF)

University of California Standards of Ethical Conduct (UCOP)

Conflict of Interest and Material Transfer Agreements (UCOP) (PDF)

Gifts/Grants Distinction: campus memo, policy documents (UCB)

Review Process

The faculty Conflict of Interest Committee is responsible for the review and assessment of financial disclosures related to research projects. 

guidelines for the review process

Committee membership and meeting schedule

Record Retention

Record Retention Requirements

Other Resources

Association of American Medical Colleges (AAMC): Financial Conflicts of Interest in Clinical Research

Association of American Universities (AAU): Conflicts of Interest

Council on Governmental Relations (COGR): Conflict of Interest Publications
Conflict of Interest

State of California Financial Disclosure

State of California law requires disclosure of financial interest in the sponsor of a research project: the donor of a research gift; and, under certain circumstances, the provider of materials under a Material Transfer Agreement (MTA) when that sponsor, donor, or provider is a non-governmental source.

For research projects, the Statement of Economic Interests for Principal Investigators (Form 700-U) should accompany the proposal and Proposal Review Form to the Sponsored Projects Office or the Industry Alliances Office.

For MTAs, the Form 700-U should accompany the Material Transfer Agreement Review Form to the Industry Alliances Office.

- Briefing Sheet - State of California Requirement to Disclose Financial Interest
- Forms
  - PI's Statement of Economic Interests (State of California Form 700-U)
  - Addendum to Statement of Economic Interests: PDF / Word (700-VA)
  - Compliance Information Form for Research Gifts: PDF / Word

U.C. Policy

- Procedures for Expedited Review of Academic Disclosures
- List of Non-governmental Entities Exempt From Disclosure Requirement

UC Berkeley Policy

- UC Berkeley Policy on Research Gift Compliance
Federal Financial Disclosure

Applicants to the National Science Foundation and Public Health Service agencies (including the National Institutes of Health) must disclose project-related financial interests for themselves and all other project investigators at the proposal submission stage.

This requirement also applies to subcontracts from PHS/NIH or NSF or to other agencies that have adopted the federal requirements (the American Heart Association, the American Cancer Society, the California Institute for Regenerative Medicine, the International Vaccine Institute, UC Discovery Grants, and UCOP Special Research Programs).

- Overview of Federal Financial Disclosure Procedures - Flowchart
- Bidding Sheet - Federal Requirement to Disclose Significant Financial Interest

Forms
- Conflict of Interest Checklist (DRF Addendum): PDF / Word
- Federal Financial Disclosure Form: PDF / Word

UC Policy
- UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects

UC Berkeley Policy
- Disclosure of Financial Interests Related to Federally Sponsored Projects

U.S. Department of Health and Human Services, National Science Foundation
- National Institutes of Health: Conflict of Interest website
- Conflict of Interest Information Resources Available on the Web
What has the Conflict of Interest Committee recommended in some typical cases?
Case #1: Investigator’s financial interest is relatively modest.
Case #2: Same situation as Case #1 but investigator has an ongoing consulting relationship with the sponsor and/or equity is also involved.
Case #3: Situations involving investigator ownership of or managerial responsibilities to the company, which will sponsor the research.
Case #4: Situation where a faculty member has majority equity ownership as well as scientific and fiscal responsibility for a company, which is proposed as the subcontractor for a major portion of the work in a campus processed NIH grant with the investigator as PI. In addition the company employs the spouse of the investigator.
New Federal and 700-U Addendum financial disclosure forms ... a first look for ERSO!
Filling out State form 700-U

- State law requires all questions be answered completely
  - Common omissions: telephone number, mail code, email, academic unit, address and principal business of funder, type and date of funding, amount and date of travel and whether payment was gift or income, date of signature.

- All 700-U forms must have original, inked signature (blue ink specified in the statute)
  - electronic or “per signatures of any kind are not permitted.
  - Requirement applies whether disclosure is positive or negative
The COI office returns incomplete or incorrect forms directly to the filer to be completed and/or corrected and returned directly to COI Coordinator.
- checklist identifying each item which caused form to be returned is attached to each returned disclosure.
- questions? comments? suggestions?
Filling out the Federal Financial Disclosure form

- The information required for Federal disclosure is based on different standards and thresholds, and reaches to indirect as well as direct financial relationships.
Filling out the Federal form (cont’d.)

- For the federal form an original, inked signature is not necessary – fax or other copy is fine.
- However, the signature *must* be that of the investigator making the disclosure.
Federal form (cont’d.)

- As with the 700-U or Addendum, incomplete forms are returned to the investigator.
- questions? comments? suggestions?
Primary Changes in Proposed New PHS Regulations

- Annual disclosure of all financial interests related to investigator’s institutional responsibilities
- *De minimus* threshold of $5K income and value of equity in publicly traded companies aggregated
- *De minimus* threshold of $5K income and value of any equity in non-publicly traded company plus management positions, IP
- Report by campus of specific information related to investigator financial interest and details of management plans
New PHS regulations (cont’d.)

- Investigator training prior to expenditure of funds and every two years thereafter
- Institution responsible for assessing disclosed financial interests to determine those that are related to PHS-funded research
- Posting of significant financial interests on a publicly accessible website
Unkowns ...

- Final rule has not yet been posted and revisions, if any are unknown
- Will UCOP take the lead on a consistent, system wide process - including on-line tools to collect and report - or will each campus have to fly solo?
- Will the conflict of commitment and conflict of interest processes be combined?
- Will NSF follow suit? What about the rest of the federal agencies?