Responsible Conduct of Research Involving Humans

Conflicts of Interest (in research)

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"You're off the hook—in order to have a conflict of interest, you gotta have an interest in the first place."
UC Policies and Guidance: Conflict of Interest

- Conflicts of Time or Commitment
- Purchasing of Goods and Services
- Use of University Property and Facilities
- Personnel Related
- Inventions, Patents and Licensing
- Interactions between industry and faculty, staff, and trainees
- **Research**
  - *Financial Conflicts of Interest*
Conflict of Interest in Research

“The term ‘conflict of interest’… 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.”

American Association of Medical Colleges and AAU
Conflict of interest statement:
Senior author's promotion and first author's job depend on this study.
Conflicts of Interest

“Conflict of interest refers to situations in which employees may have the opportunity to influence the University's business decisions in ways that could lead to personal gain or give advantage to associates or firms in which employees have an interest.”

financial conflict of interest

“…an actual or potential conflict of interest exists when the reviewer(s) reasonably determine that a significant financial interest could affect the design, conduct, or reporting of the research or educational activities funded or proposed for funding by NSF.”

National Science Foundation policy - 1995
Financial Conflict of Interest

“A significant financial interest that could directly and significantly affect the design, conduct of reporting of PHS-funded research.”

*PHS regulation of Promoting Objectivity in Research (August 2011)*
Who regulates the COI disclosure, review and reporting processes?

- State of California
- Federal
- University of California
- UCLA
- Sponsors
State of California Regulations

- Applies to the PI (+ spouse/registered domestic partner and dependent children).
- Requires disclosure of financial interests in the organization (non-governmental) providing support* for research.
- Disclosure requirements triggered by all requests for support (via contracts, grants, gifts, Material Transfer Agreements)
- UCLA review must be completed before support can be accepted.

*cash and in-kind
State of California Regulations

• Requires use of State Form 700-U “Statement of Economic Interests for Principal Investigators”.

• UCLA extended application to include others who share responsibility for design, conduct or reporting of research:
  • PI identifies others who share responsibility for the design, conduct or reporting of the research using the 700-U Addendum
  • Other Investigators with financial interests complete Supplement to Forms 700-U & 700-U Addendum, or Industry Clinical Trial Specific Supplement
State of California Regulations

• Requires disclosure of:
  ▪ positions including directors, officer, partner, consultant…
  ▪ Income (>\$500)
  ▪ Investment (<\$2000)
  ▪ Loans (>\$500)
  ▪ Gifts (>\$50)
  ▪ Travel expenses
National Science Foundation Policy

• Requires disclosure of financial interests in conjunction with all requests for support for research and educational activities before proposals are submitted
• Requires disclosure by other Investigators with responsibility for the design, conduct or reporting of research
• PI discloses financial interests and identifies who must submit disclosures using UCLA Form 740, “Investigators’ Statement of Financial Interests Related to Sponsored Projects”.
• The PI and each Investigator who has Significant Financial Interests provides disclosure details on a Form 740 Supplement
• UCLA review to determine whether a financial conflict of interest exists and any required reporting must be completed before award funds can be expended.
NSF Policy (continued)

• Applied by UCLA to all federal agencies (except PHS)
• Requires disclosure of:
  ▪ Salary or other payment for services, of $10,000 or more (during the prior twelve months or anticipated in the next twelve months)
  ▪ Equity or any other investment or ownership interest exceeding either $10,000 or a 5% ownership interest
  ▪ Intellectual property interest on a patent, patent application, or copyright assigned or licensed to a party other than UC
  ▪ Investigators must disclosure financial interests that meet the NSF definitions and thresholds and they think which would reasonably appear to be affected by the research, or are in entities which might be affected by the research.
Public Health Service Regulations

- Applies to all PHS agencies (including NIH).
- Applies to the PI (+ spouse/registered domestic partner and dependent children), and other investigators who share responsibility for design, conduct or reporting or the activities.
- Annual disclosures of financial interests must be submitted/updated prior to proposal submission.
- UCLA reviews (to determine relatedness and to identify any financial conflicts of interest) and reporting processes must be completed before award funds can be expended.
Disclosures made via the UCLA electronic Disclosure Gateway (eDGE).

Require disclosure of financial interests related to the investigators institutional responsibilities *(not just research)*

Require multiple reviews:
- A determination of whether any disclosed financial interests are *related* to research activities on which the individual participates, and
- A review of related financial interests to identify *financial conflicts of interest*.

Require detailed reports to FCOI reports to sponsor.
UCLA process - COI Review Committee (CIRC)

- Faculty peer review panel
- Members appointed by the Chancellor
- Advisory to the Vice Chancellor for Research (VCR)
- Established as an independent substantive review committee under California regulations
- Serves as designated official(s) under federal regulations and policy
CIRC Charge:

- To determine if financial interests constitute financial conflicts of interest
- To determine whether the conflicts of interest need to be reduced, eliminated or managed before research support can be accepted
- To recommend, when appropriate, measures that can be put in place to reduce, eliminate or manage conflicts of interest
Focus of CIRC Review

- Nature and magnitude of the financial interests
- Ability to separate University commitments from outside activities or build firewalls
- Nature of the research project
- Role of the Investigator on the project
- Adherence to University guidelines and policies
- Right to publish and disseminate results

- Involvement of students/postdocs/fellows
- Situations in which University IP is licensed to research sponsor and/or is used in the project
- Situations in which research sponsor wants to have an on-campus presence
- Appropriate use of University facilities
- Use of human research subjects
CIRC Recommendations

- Accept research support no further action needed

- Accept research support subject to measures designed to eliminate, reduce, or manage conflicts of interest

- Do not accept support
  - If the committee recommends that the support not be accepted, and the VCR agrees, the campus cannot accept the contract, grant, gift, or MTA
Typical Management Strategies

• Disclose in publications, presentations, and informed consent forms, and to financial interests to colleagues and trainees

• Limit annual income from sponsor

• Ask investigator to recuse him/herself from recruiting and enrolling subjects, seeing unblinded data, and/or analyzing data

• Prohibit acquisition of additional equity during study

• Reduce or eliminate financial interests
  ▪ Sell stock
  ▪ Put equity into blind trust
  ▪ Resign position(s)

• Identify someone else to handle business transactions

• Oversight

• Report back to CIRC or to the Office of Intellectual Property or to the VCR
Review Challenges

- State law, NSF policy, PHS 1995 and PHS 2011 regulations not uniform
- Revised PHS COI regulations extremely complicated
- Trying to help investigators balance outside interests with University responsibilities
- Entrepreneurial activities create increased potential for conflicts of interest and conflicts of commitment
- Increasingly complex situations
Financial Interests vs. Conflicts of Interest  TAKE AWAY MESSAGE

• Terms used interchangeably by some
• The regulations make distinctions
• The existence of financial interest does not automatically mean that a financial conflict of interest exists
• Having a financial conflict of interest does not mean that research cannot be conducted