CONFLICT OF INTEREST
OVERVIEW

- PHS regulations: Salient changes
  - Institutional responsibility
  - Definition of investigator
  - Definition of research

- Tasks to be completed
  - At time of application
  - At time of award

- Subaward certifications
  - PHS and non-research activities

- Non-research activities
Background

What

“Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought” and “Responsible Prospective Contractors”, codified at 42 CFR Part 50 and 45 CFR Part 94

When

- Effective 09/26/11
- Institutions required to be in full compliance by 08/24/12
Who

- 45 CFR Part 50 applies to:
  - Institutions that apply for or receive PHS research funding (grant or cooperative agreement) and
  - Investigators who plan to participate or are participating in such research (these regulations do not apply to SBIR/STTR Program Phase I applications)

Why
- Add transparency to investigators’ disclosure, enhance regulatory compliance and oversight
Conflict of Interest on Externally Funded Projects 1.3.2

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http://www.uc.edu/af/policies.html (under Administration and Finance)

Provides additional detail
**SALIENT CHANGES TO 1995 COI REGULATIONS**

- **Changes determination of “relatedness”**
  - Before: Investigators disclosed to Institutions on outside interests that Investigators determined “would reasonably appear to be affected by the research” in coming 12 months
  - Now: Investigators disclose **ALL** outside interests related to their institutional responsibilities* in **past 12 months**; institutions must determine whether SFI is “related to the PHS-funded research”
    - SFI is related to PHS-funded research when institution determines that SFI: could be affected by the PHS-funded research or is an entity whose financial interest could be affected by the research

*Institutional responsibilities shall mean the UCEs responsibilities associated with or resulting from his or her university appointment or position. Institutional responsibilities may include but are not limited to: research; education/teaching; professional activities; administration; and services to the university and to internal and external professional organizations.
Definition of Investigator:

- The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, collaborators or consultants.

SRS Compliance Review Form

- Investigators/Key Personnel (paid and unpaid) need to be listed.
- Clinical studies: fill out human subjects box on 1st page; 2nd page: include individuals on the IRB protocol (paid or unpaid on grant) who meet investigator/key personnel definition.
Definition of Research:

- “Research” means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter and product development (e.g., a diagnostic test or drug).

- Any such activity for which research funding is available from a PHS awarding component through a grant or cooperative agreement to include research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
Key personnel/investigators must have submitted their OAR form for 2013-2014 ("IN-REVIEW" or "COMPLETED")

Completed FCOI training (CPD website: http://cpd/uc/edu): once every four years
- PHS regulations
- UC Policy
Consultants and/or collaborators at other institutions:

1. If the consultant will be going through their institution and the institution is on FDP Clearinghouse list, then their institution complies with PHS regulations
2. If the consultant is going to be paid directly from the grant, rather than thru the institution, then consultant must comply with our COI policy even if at FDP Clearinghouse institution
3. If the consultant’s entity does not comply with PHS regulations (or their COI policy is not adequate), then s/he must follow our policy

Disclosure is required at time of application for individuals outside of our institution if #2 or #3 via OAR Affiliate portal (https://webcentral.uc.edu/oarv2/index.cfm/auth/affiliate)

ONLY disclosure must be “COMPLETED” at this time
SRS will review OAR of key personnel/investigators to determine if potential CE/COI exists

If yes, then individual(s) are referred to institutional official to determine outside activity’s relatedness to research

If potential conflict of interest:

- Conflict of Interest Committee (university board)
- IRB’s COI Subcommittee (if human subjects are involved)

Must be resolved prior to expenditure of funds
At time of award or when subaward site is identified, then SRS verifies which FCOI policy is going to be followed

Following UC’s Policy--individuals meeting the definition of “Investigator” must complete the following prior to issuance of subaward:

1. Complete affiliate OAR disclosure
2. Receive FCOI training
3. Receive UC COI Policy
4. Subrecipient FCOI Certification

Required of all subawards regardless of sponsor
Activities that involve the performance of work other than research fall into this category, and that are not federally funded.

**Non-research activities (collectively defined)**
- Instruction (training, curriculum development, instruction, demonstration, efforts to improve pedagogical methods)
- Educational service (academic support of libraries, educational media services, workshops)
- Professional (non-research purpose) travel
- Professional (non-research purpose) conferences
- Public service (cooperative extension outreach, health service projects, community service programs)
- Student service (projects which involve UC students in community service activities, awards to departments/schools for support of students)
- Programs to enhance institutional resources
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