Revised Public Health Service Regulations

Quick review:

• Intended to increase accountability, add transparency, enhance regulatory compliance and effective management of financial conflicts of interest and strengthen governmental compliance oversight
• Increases disclosure, review and reporting requirements
• Requires an initial disclosure that must be updated within 30 days of acquiring or discovering any new significant financial interest, and at least annually
Revised Public Health Service Regulations

- Adds an education/training requirement
- Expands reporting requirements
- Adds a new public accessibility requirement
- Adds new monitoring requirements
Revised Public Health Service Regulations

• Require that investigators disclose SFIs that are related to their institutional responsibilities

• Require that UCLA engage in a two-step review of disclosed financial interests to determine:
  ▪ if any disclosed significant financial interest is related to the PHS research (could be affected by the research or is in an entity that whose financial interest could be affected by the research), and then
  ▪ if any disclosed significant financial interest constitutes a financial conflict of interest
What Are Significant Financial Interests?

- Anything of monetary value related to the investigator’s institutional responsibilities including but not limited to:
  - Salary or other payment for services and the value of equity in a publicly traded entity >$5,000 over the past 12 months
  - Salary or other payment for services >$5,000 or any equity in a privately held entity over the past 12 months
  - Intellectual property rights (e.g. license fees or royalties) paid by any entity, other than UC, upon receipt of income related to such rights (>5,000 in the past 12 months)
  - Travel of any $ value paid for, or reimbursed by, an outside entity
Institutional Responsibilities

“For the purposes of this policy, the term institutional responsibilities is defined as teaching/education, research, outreach, clinical service, and University and public service, on behalf of the University of California performed in the course and scope of the investigator’s UC appointment”

(UC and UCLA definition)
What Is a Financial Conflict of Interest?

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

(PhS regulations)
Prior to the Institution's expenditure of funds under the PHS funded research project, the designated official shall review disclosures of Significant Financial Interests (SFI) related to Institutional responsibilities.

No further review needed. → Unrelated → Are the SFIs related to the PHS funded research?

May Be Related

RPC staff reviews.

Related? → Yes

Are the SFIs FCOIs?

No

Implement management plan.
Progress Since March

• PHS contracts and grants will be phased in:
  • The regulations will affect PHS awards made on or after August 24, 2012
  • The regulations will affect proposals submitted on or after August 24, 2012
  • Ongoing awards will become subject to the revised regulations as progress reports, competing renewal applications, proposals for supplemental funding or requests for no-cost time extensions are made on, or after August 24, 2012
Progress Since March (continued)

• UCLA Policy 926 “Public Health Service Regulations on Objectivity in Research” drafted
• Developing content for a short education/training program that briefs PHS investigators on:
  - UCLA’s Policy
  - Investigators’ Disclosure Responsibility
  - The PHS COI regulations
• Planning to embed the training/educational program into the web-based disclosure system
Development of an E-Solution

• Working with Huron's Click™ Portal to customize the Conflict of Interest Module starter site

• Designing smart forms for initial disclosure and required updates

• Working with OCGA and OIP-ISR to develop processes for exchanging critical information
Naming the E-Solution

- Considered (and rejected)
  - eCOI
  - Financial Interest Disclosure System (eFIND)
  - eGAD or eGADs
  - Styx

- We need your good ideas
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