PHS COI and UC Compliance: How Are We Doing Now?

This session will include an interactive discussion of significant compliance challenges identified by session attendees. Possible topics include determining bias, travel reporting, subrecipient monitoring, retrospective reviews, others, and options that UC campuses and non-UC institutions have developed, or need to develop, to respond to these challenges.

Presenters: Jeff Hall (UCSF) Grace Park (UC) (South only); Elizabeth Kaye (UCSD) (North only)
2013 UC Compliance & Audit Symposium

Why did the PHS/NIH change its rules on conflict of interest?

Since the current regulations were published 17 years ago:
- Biomedical and behavioral research has grown much more complex
- Interaction among government, research institutions, and the private sector has increased
- Increased public scrutiny required a more rigorous approach to investigator disclosure, institutional management of financial conflicts, and federal oversight

Revised Public Health Service (PHS) Procedures

University of California
Federal Policy

- National Science Foundation (NSF)
- Public Health Service (PHS)

Revisions issued: August 25, 2011
Implemented: August 24, 2012

- Proposals submitted on or after August 24, 2012
- Notice of Award issue date on or after August 24, 2012

Federal Policies

On and after August 24, 2012

Investigator: Project Director or Principal Investigator and any other person, regardless of title or position, responsible for design, conduct, or reporting of research being funded
Are existing awards subject to the new PHS Rule?

- The new Final Rule will apply to each grant or cooperative agreement with a Notice of Award issue date after August 24, 2012 (including noncompeting continuations) and to solicitations issued and contracts awarded after August 24, 2012 that are for research.

- UC had the option to apply the new Final Rule to all active PHS awards on a single date (or on or before 8.24.12) on all PHS-funded awards, or to implement the regulations sequentially on the specific award date of each individual project. We chose the latter “rolling implementation” option.

*Also applies to awards where PHS is prime sponsor and the following organizations that follow PHS regulations:

- American Cancer Society
- American Heart Association
- Arthritis Foundation
- Susan G. Komen Foundation
- Alliance for Lupus Research
- Juvenile Diabetes Research Foundation
- Lupus Foundation of America

PHS Agencies include NIH, AHRQ, CMS, CDC, FDA, SAMHSA, HRSA, AoA, ACE, BARDA, IHS, OGA, ASPR, OMIH, ASPR, OPA, ORI, OWH, OPA, and others.

Main Requirement Changes

Institutional Responsibilities

Less Exclusions

$5,000 Threshold

Zero Threshold

Training Requirement

30 Days to Update
All Significant Financial Interests (SFIs) related to Investigator's institutional responsibilities must be disclosed. Institutional Responsibilities include teaching/education, research, outreach, clinical service, training, and University and public service, on behalf of UC and directly related to those credentials, expertise and achievements upon which the Investigator's UC position is based.

Investigators
- Can only exclude income & travel financial interests from federal, state, local agencies, US institutions of higher education and affiliated research institutes, academic teaching hospitals, and medical centers.
- Must now also disclose for training awards, fellowship awards and for no cost time extensions (still exclude SBIR & STTR Phase I awards).
- Exclude income from UC Regents, mutual funds, and retirement accounts.

Less Exclusions

Significant Financial Interests (SFIs) includes one or more of the following financial interests of the Investigator, Investigator’s spouse/registered domestic partner, and/or dependent children:

- **Publicly Traded Entity:**
  - Income > Equity > $5,000

- **Non-publicly Traded Entity:**
  - Income > $5,000

- **Intellectual Property** (not assigned to UC Regents):
  - Income > $5,000

**$5,000 Threshold**
Significant Financial Interests include:
- Any equity in non-publicly traded entity
- Any sponsored or reimbursed travel (note exclusions)

Zero Threshold

All Investigators must complete COI training prior to engaging in PHS-funded research and every 2 years

- Until all Investigators listed on PHS Disclosure form complete training, PHS awards cannot be released (i.e. training must be completed prior to award stage)

Training Requirement

Investigators must disclose newly acquired/discovered SFIs (including sponsored or reimbursed travel) related to institutional responsibilities within 30 days of acquisition or discovery
- Failure to disclose may result in retrospective review

30 Days to Update
Note: If an Investigator anticipates sponsored or reimbursed travel in the next 12 months, can complete the PHS Appendix to prescribe travel and avoid the 30 day update requirement.
Summary

Changes to Procedure

- Disclose at time of application
- Proposals cannot be submitted until PHS Disclosure is completed by ALL Investigators
- Complete training requirement prior to award stage
- Extended review procedures
- Creation of new forms
A special thank you to:

Nadia Wong, UC Irvine Conflict of Interest Analyst,
for her principal authorship and design of the Prezi presentation from which most of these slides are derived.

Questions?

PHS Financial Conflict of Interest Page:
http://grants.nih.gov/grants/policy/coi/