

## 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 (UCOP) Grace Park (UC) (South only) Elizabeth Boyd (UCSF) (North only)  
2013 UC Compliance & Audit Symposium

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## 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

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## Revised Public Health Service (PHS) Procedures



University of California

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July  
1995

**Federal Policy**

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

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**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

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On and after August 24, 2012

**Federal Policies**

**NSF**  
Procedural changes  
- Due at time of application

**PHS\***  
Significant changes

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

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### 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 (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.

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\*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, SAMSHA, HRSA, AoA, ACF, BARDA, IHS, OGA, ASPR, OMH, ASPR, OPA, ORI, OWH, OPA, and others.

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### Main Requirement Changes

<p><b>Institutional Responsibilities</b></p> <p><b>\$5,000 Threshold</b></p> <p><b>Training Requirement</b></p>	<p><b>Less Exclusions</b></p> <p><b>Zero Threshold</b></p> <p><b>30 Days to Update</b></p>
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All Significant Financial Interests (SFIs) related to Investigator's institutional responsibilities must be disclosed

**Institutional Responsibilities**

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.

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**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**

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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**

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Significant Financial Interests include:

- Any equity in non-publicly traded entity
- Any sponsored or reimbursed travel (note exclusions)



Zero Threshold

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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

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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

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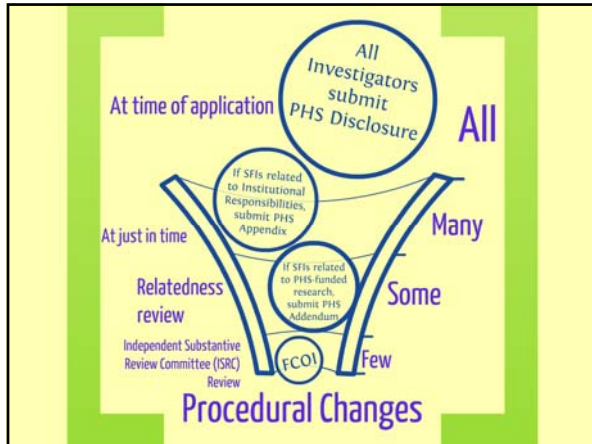
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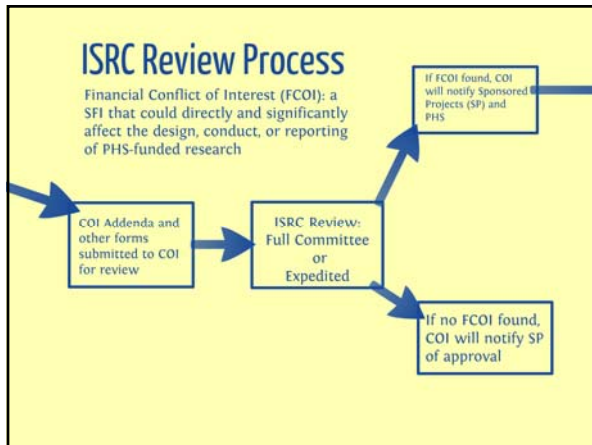
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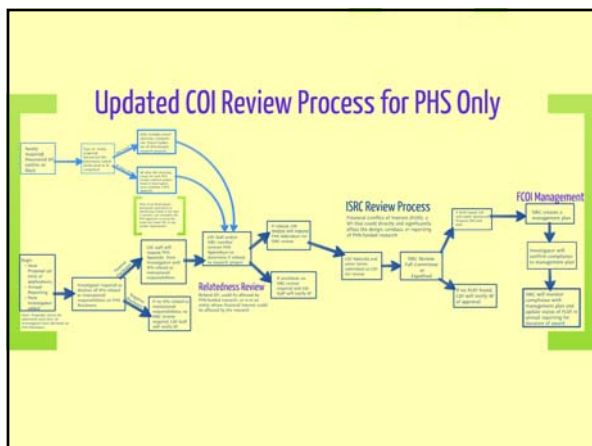
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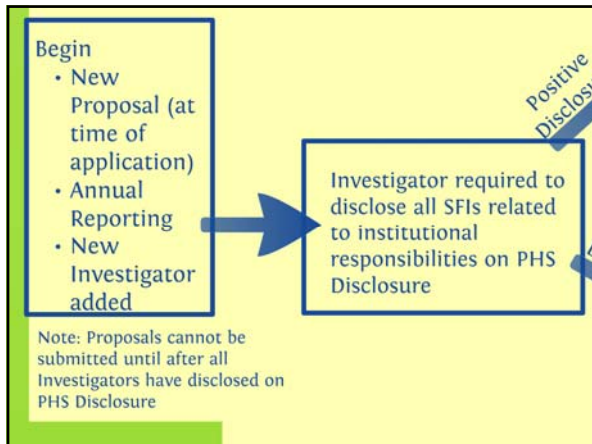
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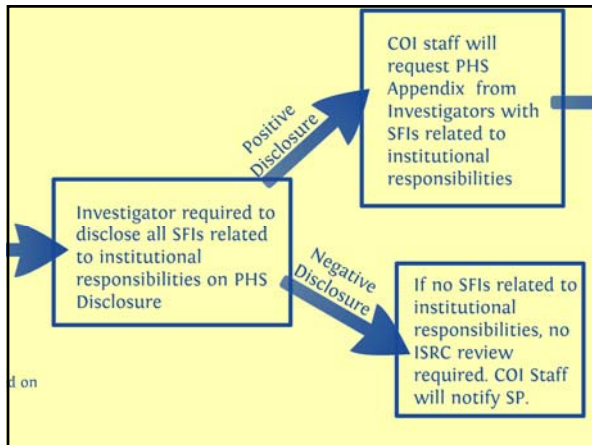
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Note: If an Investigator anticipates sponsored or reimbursed travel in the next 12 months, can complete the PHS Appendix to prescribe travel and avoid the 30 day update requirement

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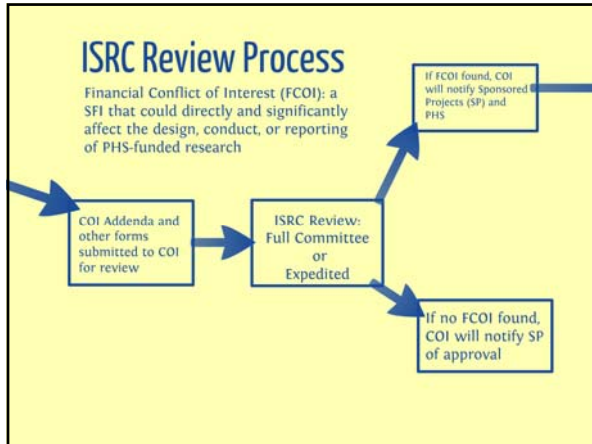
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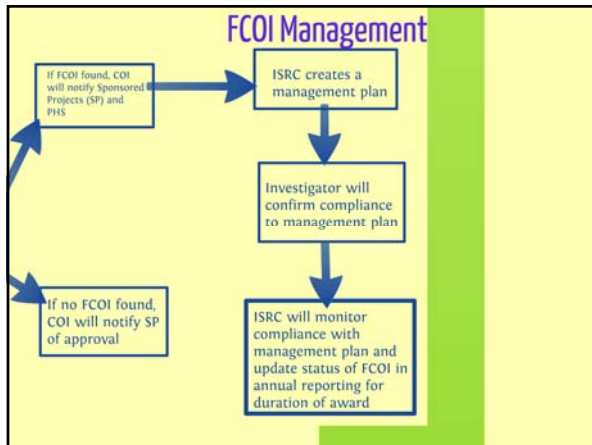
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Newly Acquired/ Discovered SFI (within 30 days)

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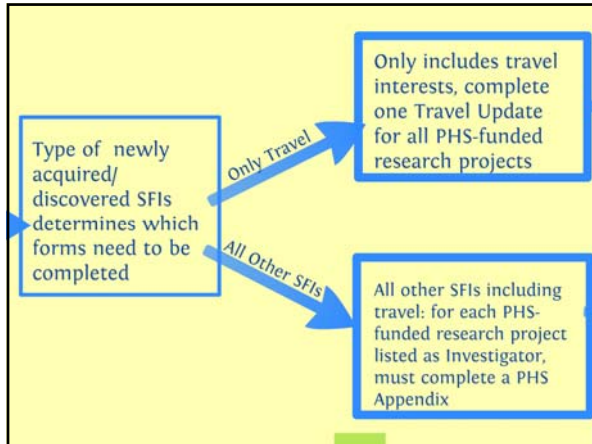
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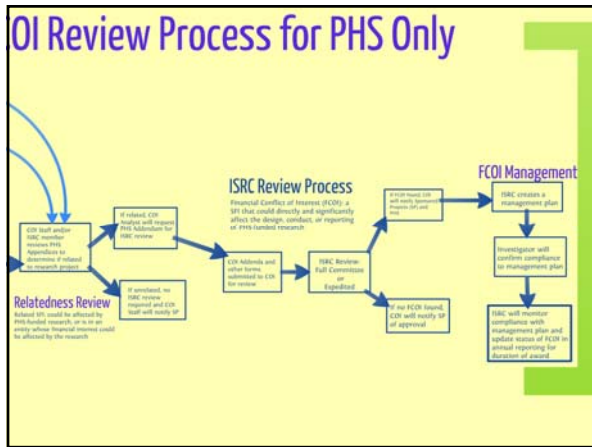
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## Summary

### 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

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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

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**Questions?**

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

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