

 **BERKELEY LAB**
LAWRENCE BERKELEY NATIONAL LABORATORY

 U.S. DEPARTMENT OF **ENERGY**

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 **RIIO** RESEARCH AND INSTITUTIONAL INTEGRITY OFFICE

Molly Stoufer

EMPLOYEE CONCERNS
CONFLICT OF INTEREST
RESEARCH INTEGRITY

Public Health Service/NIH Conflict of Interest Regulations
November 2012

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Introductions

We have primary responsibility for Employee Concerns, Research Integrity, and Conflict of Interest.

I am here today to talk about conflict of interest, specifically as it relates to PHS/NIH funded research

Review: Changes in PHS/NIH Disclosure Requirements



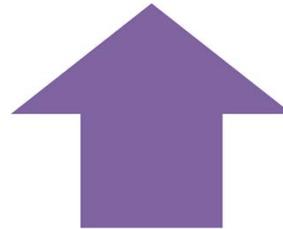
Lower Thresholds

- > \$5k income
- > \$5k equity
- Any equity in non-publicly traded company



Expanded Scope

- All interests related to "institutional responsibilities", not just those related to the proposed research



These went into effect on or before August 24 2012.

What are investigators required to disclose?

- **Investigators are expected to disclose all Significant Financial Interests that are related to their Institutional Responsibilities.**
- **Investigator** means 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.
- **Institutional Responsibilities** means research, teaching/education, outreach, clinical service, and University and public service performed on behalf of the University of California which are within the course and scope of the Investigator's Berkeley Lab/University of California employment/appointment.

The definition of investigator has not changed from NIH's prior COI regulations. The PI must determine who meets this definition. It is possible that in past reporting, PI's have not considered this as broadly as may be appropriate.

Investigator may include collaborators or consultants.

What are investigators required to disclose?

- **For a publicly traded entity**
All income which, when added to the value of any equity interest in the entity, exceeds \$5,000.
- **For a non-publicly traded entity**
Income that exceeds \$5,000, or any equity interest in the entity.

Significant Financial Interest under the new_PHS rules means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or registered domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

The amounts of money involved are very low.

What are investigators required to disclose?

- **Intellectual Property Rights**
Income greater than \$5k from IP **not owned** by the Regents of the University of California
- **Travel**
Travel reimbursed or sponsored by a an entity other than a government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The threshold for travel disclosure is under revision.

Government entities include federal, state, or local

Example: Travel reimbursement to attend an American Heart Association grant review panel or to a clinical trial investigator's meeting must be disclosed.

When are investigators required to disclose?

- **At the time of the application for PHS funding;**
and
- **Within thirty days** of discovering or acquiring any new Significant Financial Interest; and
- **At least annually** throughout the period of the award.
- **Before joining an on-going PHS-funded research project**, new Investigators must also complete a disclosure of Significant Financial Interests.

Note that under DOE's COI requirements, all outside employment and consulting requires prior approval.

Additional Points on Travel Disclosures

- At the time of application for funding, Investigators must disclose travel received during the past 12 months, and anticipated in the upcoming 12 months
- All subsequent travel payments must be disclosed within 30 days of receipt
- Declared value of travel can be estimate rather than exact cost

Review: Additional PHS Requirements



- Training on new policy every four years
- Publish online or make available upon request facts of cases that involve significant conflicts of interest
- Non-compliance results in retrospective review and increase in frequency of required training

UC COI for Researchers Training fulfills the training requirement; training was rolled out to employees in S&E job classes, and post docs, last Friday, July 27.

Review: Changes in PHS/NIH Disclosure Requirements



Topic	1995 Regulations	2011 Final Rule
Significant Financial Interests (SFI) threshold	De minimis threshold of \$10,000 for disclosure generally applies to payments or equity interests	De minimis threshold of \$5,000 for disclosure generally applies to payments for services and/or equity interests. Includes any equity interest in non-publicly traded entities.
Which SFIs need to be disclosed (once the threshold is met)	Only those SFI the Investigator deems related to the PHS-funded research.	All SFI related to the Investigator's institutional responsibilities.
Excluded from disclosure requirement	Income from seminars, lectures, or teaching, and service on advisory committees or review panels, for public or nonprofit entities	Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
Types of SFI excluded	All forms of remuneration are included – specific questions such as mutual funds and blind trusts are addressed in FAQ on the NIH website.	Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
Travel reimbursements and sponsored travel	Travel reimbursement is not mentioned explicitly in the regulations but is not excluded from the SFI definition.	Disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.
Information on an Identified Financial Conflict of Interest (FCOI) reported by the Institution to the PHS Awarding Component	<ul style="list-style-type: none"> Grant/Contract number Project Director/Principal Investigator (PD/PI) or Contact PD/PI Name of Investigator with FCOI Whether FCOI was managed, reduced, or eliminated 	<p>INITIAL REPORT</p> <p>Requirements in 1995 reg, plus:</p> <ul style="list-style-type: none"> Name of the entity with which the Investigator has a FCOI Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; ams between \$20K-\$100K by increments of \$20K; ams above \$100K by increments of \$50K or statement that a value cannot be readily determined. A description how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research Key elements of the Institution's management plan <p>ANNUAL REPORT</p> <ul style="list-style-type: none"> Status of the FCOI Changes to the management plan

Review: Changes in PHS/NIH Disclosure Requirements (cont)



Subrecipient Institutions/Investigators and Reporting of identified FCOIs	Institutions must take reasonable steps to ensure that Investigators working for subs comply with the regs by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regs	<ul style="list-style-type: none"> • Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements • Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations.
Public Accessibility	No requirement	Make certain information available concerning identified FCOIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule.
FCOI training	No requirement	<p>Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances:</p> <ul style="list-style-type: none"> • Institutional FCOI policies change in a manner that affects Investigator requirements • An Investigator is new to an Institution • An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.
Retrospective Review ("Mitigation plan," discussed in NPRM)	Not mentioned	Institution is required to conduct a retrospective review in those cases of non-compliance with the regulation but is not required to report the review to the PHS Awarding Component. The Institution will be required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

Implementation Information

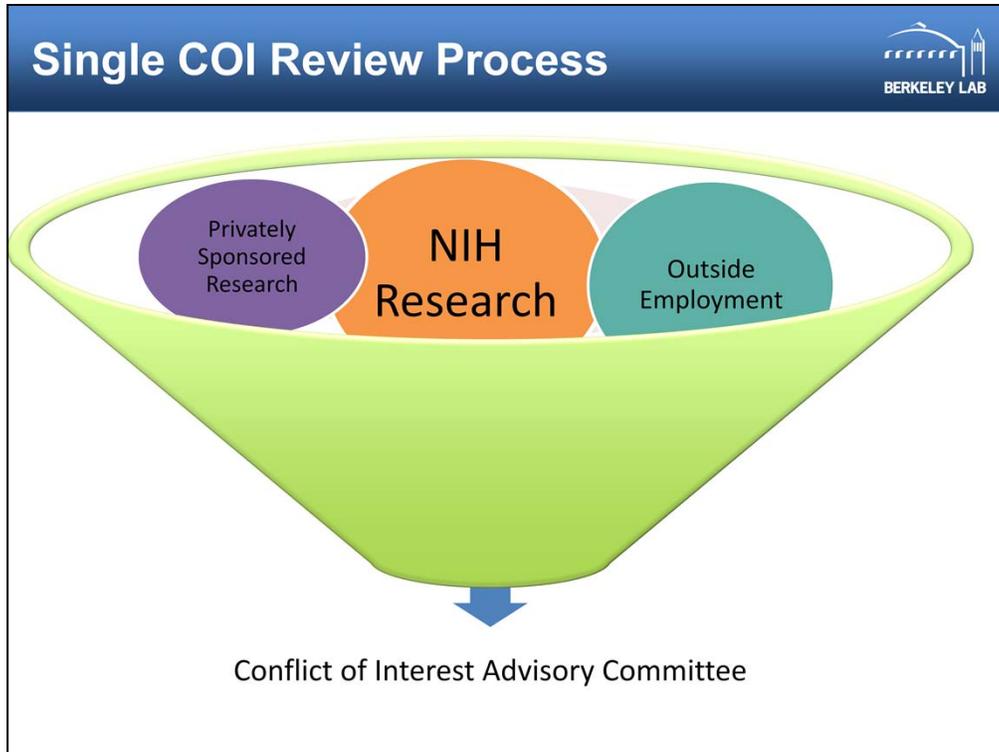
- 95% of researchers Lab-wide completed **training** that satisfies PHS requirements
 - New hires enrolled automatically
 - Continue to verify training completion through Division contact or RIIO
- Current forms available on RIIO website at <http://www.lbl.gov/Workplace/RIIO/coi/phs.html#forms>
 - Make sure to use current forms to avoid delays in processing

Reminders

- Make sure to use current forms to avoid delays in processing
- It is very important to check to correct box in eSRA regarding positive disclosures; this is our primary notification that COI review is required.
- Remind your investigators of new rules. We are seeing fewer disclosures than anticipated.

What's Next?

- Electronic "DFI-3" is in development
- We welcome suggestions for streamlining travel disclosures



Disclosures arise out of different policies, but LBNL will continue to utilize a single review process.

Conflict of Interest Advisory Committee Reviews and makes recommendation to Deputy Director Horst Simon, who is the deciding official.

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Questions?
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Meredith Montgomery and Molly Stoufer
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You can find us at 50A-4117