

## PHS Financial Conflict of Interest (FCOI) Requirements for UC San Diego PHS-Funded Investigators

As of August 24, 2012, new, more stringent rules for financial conflict of interest (FCOI) in all research sponsored by the Public Health Service (PHS), including the National Institutes of Health (NIH) will be in effect. Under Federal law, UC San Diego must be in compliance with all of the new requirements by August 24, 2012. The new rules also apply to a handful of non-federal sponsors as well.

This means that UC San Diego must correspondingly change our processes and procedures for PHS-proposals and awards. This change impacts our Investigators as well as our subrecipients, and potentially our consultants or collaborators/service providers as well.

All PHS-funded Investigators (i.e., the Project Director/Principal Investigator, any person identified as Senior/Key Personnel in a grant application, progress report, or other report submitted to a PHS agency, and others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research) will be required to disclose any Significant Financial Interests (SFIs) related to their Institutional Responsibilities.

The revised regulation includes comprehensive changes, focusing on these areas in particular:

- Definition of Significant Financial Interests
- Disclosure of Significant Financial Interests Related to Institutional Responsibilities
- Mandatory Investigator Training
- Disclosure Requirements for Subrecipients
- Disclosure of the Occurrence of Sponsored and Reimbursed Travel

**The new regulations apply only to grants and cooperative agreements awarded on or after August 24, 2012, including noncompeting continuing awards.**

The new FCOI policy applies to any award with a PHS funded sponsor including:

- research contracts
- research grants
- career development awards
- center grants
- individual fellowship awards
- Infrastructure awards
- institutional training grants
- program project or research resources awards
- conference grants.

### Available Resources

UC San Diego Conflict of Interest Office  
<http://coi.ucsd.edu> or [info@coi.ucsd.edu](mailto:info@coi.ucsd.edu)

UC PHS Conflict of Interest Training  
<http://coi.ucsd.edu/Training/Overview.htm>  
FDP Sample PHS Compliant Conflict of Interest Policy  
[http://sites.nationalacademies.org/PGA/fdp/PGA\\_061001](http://sites.nationalacademies.org/PGA/fdp/PGA_061001)

NIH Resources  
[http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)

UC Policy on Disclosure of Financial Interests Management of Conflict of Interest Related to Public Health Services Sponsored Awards for Research  
<http://www.ucop.edu/research/policies/documents/12-0133-phs-researcher-financial-disclosure.pdf>

# How Will These Changes Affect You?

*These are the changes that will affect all UC San Diego's PHS-funded Investigators with a Notice of Award on or after August 24, 2012.*

## Disclosure Requirements

- All Investigators participating in PHS-funded research must disclose at the proposal submission stage and at least annually, all significant financial interests (SFIs) related to your **Institutional Responsibilities**.
  - Institutional Responsibilities include teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California which are in the course and scope of your UC appointment/employment.

Significant Financial Interests (SFI) include:

- Income received from a publicly-traded entity during the 12 months prior to disclosure which, when combined with the value of any equity interest you hold in the entity, exceeds \$5,000
- Income received from a non-publicly traded entity during the 12 months prior to disclosure that exceeds \$5,000 OR any equity interest you hold in that entity
- Income received from an entity, other than UC, for intellectual property rights and interests during the 12 months prior to disclosure that exceeds \$5,000
- Travel of any amount paid for or reimbursed by a for-profit or non-profit entity, including professional organizations and foreign universities.

Additionally, you must disclose within 30 days if there have been any changes to your SFIs during the course of a project, and complete NIH-compliant PHS for COI training every four years.

## PHS FCOI Disclosure Process

The Conflict of Interest Office has developed a three-step process to implement the disclosure, review and reporting requirements of these regulations.

This new process has been designed to reduce an Investigator's financial reporting requirements at the initial proposal submission stage for new and competing continuation/renewal proposals. More detailed financial information will not be collected from Investigators unless it is determined that a proposal is likely to be funded, generally when a Just-in-Time (JIT) or similar request is received. This will allow Investigators and the Independent Review Committee (IRC) on Conflict of Interest to concentrate efforts on disclosure and review associated with projects that are likely to be funded, and reduce the administrative burden on investigators at the time a new or competing continuation/renewal proposal is submitted.

## Step 1— At the Time of Proposal Submission:

- At the time a PHS proposal is submitted, any individual on the proposed project who meets the definition of Investigator is required to provide basic identifying information and responses to an initial set of four screening questions pertinent to the new federal regulations for disclosure of significant financial interests on the **Financial Interest Disclosure for PHS-Funded Research**. This form must accompany the proposal when it is submitted to HSSPPO/OCGA/SIO-OCGA.
- ***Unless a proposal is likely to be funded, this is the extent of the financial disclosure requirement for most investigators.***

## Step 2—After the Just-In-Time or Notice of Award Notification is Received:

- If and when a proposal receives a Just-In-Time (JIT) request or some other indication from PHS that indicates it is likely to be funded and when the **Financial Interest Disclosure for PHS-Funded Research** has a "Yes" response, only those individual(s) with a "Yes" response will be contacted by the Conflict of Interest (COI) Office to complete and submit the **PHS Financial Conflict of Interest Disclosure Supplement**. The Supplement contains a set of questions, the answers to which will be used by to determine whether or not a disclosed SFI is related to the PHS research project to be funded.
- ***Only those investigators for whom relatedness has been established will move to Step 3.***

## Step 3:

- Any Investigator with a related SFI as determined by their responses on the **PHS Financial Conflict of Interest Disclosure Supplement** will be reviewed by the IRC.
- The IRC will review the proposal, the PHS Financial Disclosure and Supplement forms and any other pertinent information which may be needed to determine whether the related SFI could directly and significantly affect the design, conduct or reporting of the PHS-funded research. If so, a management plan will be put in place in order to provide reasonable expectation that the PHS-funded research will be conducted free of bias. This review will occur at the regularly scheduled monthly meetings of the IRC.

## Questions?

Please contact the Conflict of Interest Office at: [info@coi.ucsd.edu](mailto:info@coi.ucsd.edu) or <http://coi.ucsd.edu> if you have questions or need additional information.