

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) are in effect. The new rules also apply to a handful of non-federal sponsors as well, such as the American Heart Association and the American Cancer Society.

The new regulations apply only to PHS grants and cooperative agreements awarded on or after August 24, 2012. In order to comply with the new regulations, a new electronic disclosure form has been created and is required for each PHS proposal and award: **Financial Disclosure for PHS-Funded Research**.

Conflict of Interest disclosure processes for all other extramural support (i.e., non-governmental sponsored research and non-PHS governmental sponsored research) remains unchanged. Please continue to use the applicable 700-U and/or 9510 COI disclosure forms.

These new regulations require changes to our processes and procedures for PHS proposals and awards impacting our Investigators as well as our subrecipient investigators, and potentially our consultants, collaborators/service providers.

Who Must Disclose

PHS has changed the definition of "Investigators:" 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) are required to disclose any Significant Financial Interests (SFIs) related to their Institutional Responsibilities.

Timing of Disclosure

Disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity **before the application for initial, continuation, renewal or supplemental funding is submitted**.

Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:

- Within 30 days of the occurrence of any sponsored or reimbursed travel
- Within 30 days of acquiring or discovering any new SFI and/or the change in an existing SFI; and
- At least annually.

New Investigators must complete a **Financial Disclosure for PHS-Funded Research** before joining an ongoing PHS Research Activity.

Research Activities Requiring FCOI Disclosure

The new regulations apply to any proposal or award with a PHS-funded sponsor and include:

- 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.

What Significant Financial Interests (SFI) Must Be Disclosed

Investigators must use the **Financial Disclosure for PHS-Funded Research** to disclose income, equity, and intellectual property rights interests meeting certain thresholds, and the occurrence of any sponsored and or reimbursed travel related to their Institutional Responsibilities. Institutional Responsibilities include the teaching/education, research, outreach, clinical services, training and University and public service performed on behalf of the University and directly related to those credentials, expertise and achievements upon which your University appointment/employment is based.

Available Resources

Disclosing Financial Interests PHS Sponsored Research
<http://blink.ucsd.edu/sponsor/coi/disclosing/phs.html>

UCSD PHS Conflict of Interest Training
<http://blink.ucsd.edu/sponsor/coi/training.html>

UC Policy on Disclosure of Financial Interest and Management of Conflict of Interest Related to Public Health Services Sponsored Awards for Research
http://policy.ucop.edu/doc/2500558/PHS_COI

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.

PHS FCOI Disclosure Process

The Conflict of Interest Office, in conjunction with other UC colleagues, 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 funded. This will allow Investigators and the Independent Review Committee (IRC) on Conflict of Interest to concentrate efforts on disclosure and review associated with awarded projects 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/Non—Competing Renewal 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 be submitted to the COI Office **before** any proposal can be submitted to the funding agency.
- ***Unless a proposal is funded, this is the extent of the financial disclosure requirement for most investigators.***

Step 2—After the Notice of Award or Notification from the Contracting Office is Received:

- If and when a proposal receives an indication from PHS that indicates funding is imminent 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 the IRC makes such a determination, then when possible, 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.

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 their **Institutional Responsibilities**.
 - Institutional Responsibilities include the teaching, education, research, outreach, clinical services, training and University and public service performed on behalf of the University and directly related to those credentials, expertise and achievements upon which their University appointment is based.
- 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 held in the entity, exceeds \$5,000,
 - Income received from a non-publicly traded entity, including non-profit organizations, during the 12 months prior to disclosure that exceeds \$5,000 OR any equity interest held 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, Investigators must disclose within 30 days if there have been any changes in their SFIs during the course of a project, and complete PHS COI-compliant training every four years.

Questions?

Please contact the Conflict of Interest Office at:
Info-coi@ucsd.edu or (858) 534-6465