New Federal COI Regulations Impose New Disclosure and Training Obligations for Investigators Conducting PHS-sponsored Research

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**Covered Agencies and Sponsors:**
On August 24, 2012, new and more stringent rules for the disclosure of financial interests will take effect for all research sponsored by the Public Health Service (PHS), including the National Institutes of Health (NIH). The new rules also apply to a handful of non-federal sponsors, including the American Cancer Society and the American Heart Association. To access a list of all agencies and sponsors who have adopted these new rules, click here. Collectively, these agencies and sponsors are referred to herein as “covered” agencies.

**New Scope of Disclosures:**
The prior rule only required disclosures of financial interests that are related specifically to your research activities. The new Federal COI rule (FCOI) has substantially broadened this initial disclosure obligation. Specifically, all investigators are now required to disclose to the Institution (UC Davis’ Research Compliance and Integrity) financial interests (of you, your spouse or registered domestic partner, and dependent children) that reasonably appear to be related to your institutional responsibilities, including activities such as teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**New Monetary Thresholds for Reporting:**
The new rule also establishes lower monetary thresholds that trigger an investigator’s obligation to disclose. The prior PHS rules generally contained reporting thresholds that exceeded $10,000. Now, as outlined further below, receipt of more than $5,000 in remuneration from any source (with the exception of federal and state agencies, U.S. colleges and universities, and academic medical centers) that reasonably appears to be related to your institutional responsibilities must be disclosed to the Institution at the time of proposal submission. In addition, stock or equity ownership in a publically traded company that exceeds $5,000 (or any amount for a non-publically traded company) must be disclosed if such financial interest is related to your institutional responsibilities. Also, investigators must disclose any and all travel (with the exceptions indicated below) that is related to their institutional responsibilities and that is paid for or reimbursed by any entity regardless of the monetary amount involved. Financial interests that meet this definition and thresholds are deemed “significant financial interests” (SFI).

**Who Must Disclose:**
The new FCOI rule requires the PI, and any other person who has responsibility for the design, conduct, or reporting of research to file separate Disclosures. The new rules (both training and disclosure) also apply to the same category of investigators who are involved in the project on sub awards. Please note that you MUST complete a Disclosure even if you do not have any reportable SFIs.
When must Disclosures be Made:

- **Initial Disclosures**: For investigators who are presently performing research funded by a covered agency, a new/initial Disclosure must be made before receipt of a Notice of Award (dated after August 24, 2012) for additional funding, including non-competing continuation progress reports. For proposals submitted after August 24, 2012, disclosures must be made no later than at the time of the submission of the funding application.

- **Annual Disclosures**: A Disclosure must be updated at least annually during the period of the award.

- **Disclosure of New SFIs**: A Disclosure must be updated within 30 days of the investigator acquiring or identifying a new SFI or to disclose a SFI that was not disclosed timely. A new SFI can be acquired, for example, through purchase, marriage, or inheritance. A new SFI also includes a different type or nature of SFI than what had previously been disclosed from the same source that meets or exceeds the threshold (e.g., Investigator now receiving royalty payment in addition/or instead of consulting fees).

As a UC Davis “investigator” (as broadly defined by PHS), it is your responsibility to timely disclose all your SFIs in a manner that is consistent with the scope and breadth of the new FCOI regulations.

**Definition of a Significant Financial Interest (SFI)**
Initially, a “financial interest” is anything of monetary value, whether that value can be easily determined or not, that is held by you, your spouse or registered domestic partner, and dependent children. Any such “financial interest” becomes a “significant financial interest” that must be disclosed when it:

1. **Reasonably appears to be related to or is in the same field of expertise as your institutional responsibilities.** *(This includes the teaching/education, research, outreach, clinical services, and University and public service you perform in the course and scope of your UC Davis appointment)*;

   AND

2. **Meets any of the following reporting categories and thresholds:**

   a. Is income from any publicly traded entity where the total amount received over the past 12 months exceeds $5,000; or

   b. Is an equity interest in any publicly traded entity where the value of such equity interest at the time of this disclosure exceeds $5,000; or

   c. Is an equity interest in any publicly traded entity from which you (or any immediate family member) have also received any income in the past 12 months where the amount of income and present value of the equity interest, when totaled, exceeds $5,000; or

   d. Is income from any non publicly traded entity where the total amount received over the past 12 months exceeds $5,000; or

   e. Is an equity interest of any value in any non-publicly traded entity; or

   f. Is income or payments, received over the past 12 months, for any intellectual property rights and interests (e.g. patents, copyrights, assigned or licensed to a party other than the regents) exceeding $5,000; or

   g. Is travel that has been sponsored by any entity, or for which you have received any travel reimbursement or payments regardless of value or amount.
A Significant Financial Interest DOES NOT include:

1. Interests in mutual funds or other investment vehicles such as retirement funds as long as you do not directly control the investment decisions.

2. Payments made to you by UC for salary, stipends, royalties, honoraria, reimbursement of expenses or any other remuneration received from the University.

3. Income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.

4. Travel costs paid for or reimbursed by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.

What Happens After You Make Your Disclosure:
If your Disclosure identifies one or more SFIs, the Institution is then required to determine whether the disclosed financial interest could be affected by the research and, if so, whether the financial interest could directly and significantly affect the design, conduct, or reporting of the research. Depending on the type and nature of the SFI(s), either the Research Compliance and Integrity (RCI) staff will make this determination, or the UC Davis Conflict of Interest Committee (COIC) will consider the Disclosure and decide whether some sort of management plan is warranted.

You should understand that not all SFIs are automatically a financial conflict of interest (FCOI). RCI and/or the COIC will continue to review your financial disclosures and relevant features of any related research projects to determine if an SFI rises to the level of a “financial conflict of interest.” Further, in most cases, the COIC will be able to “manage” almost all disclosed FCOIs so that the research project can be accepted and funded by the sponsor.

How Does an Investigator Make a Disclosure:
The Office of Research is presently developing a “user-friendly” online disclosure that complies with the regulations. This on-line form will go “live” on August 24, 2012, and will be accessible at researchcoi.ucdavis.edu.

Mandatory Training Requirement
On August 6, 2012, you may have received an e-mail from Staff Development & Professional Services (sdps@ucdavis.edu) regarding training for general conflict of interest in research (2012 Compliance and Conflict of Interest for Researchers Briefing (COIR)) that is required by the Office of the President. A component of this training satisfies the mandatory training under the new FCOI rules.

All investigators who are engaged in any research funded by a covered entity as of August 24, 2012 must complete this training prior to the receipt of any new funds from the covered entity via a Notice of Award.

All investigators who will engage in research funded by a covered entity after August 24, 2012 must complete the training prior to engaging in the research following receipt of funds via a Notice of Award. Any investigator who is added to an existing research project after August 24, 2012 must complete the training prior to engaging in any research on the project.

If you were not contacted to complete the 2012 Compliance and Conflict of Interest for Researchers Briefing (COIR) and are required to complete PHS training under the new FCOI rules, you may satisfy the training requirement by going to UC Davis Learning Management System and searching for "COI-PHS." Please follow the instructions below:

1. Log in to the UC Learning Center using your UCD LoginID and Kerberos password
2. Search for keyword "COI-PHS" in the UC Learning Center search bar on the left of your screen.

3. Select the Conflict of Interest class, click "Start." The online course will then launch.

Alternatively, you soon will be able to satisfy this training obligation through CITI training (the training module is currently in development and a link will be provided once available). It is imperative that you complete this mandatory training in a timely fashion to avoid any funding delays.

Additional Information and Resource Materials
The following additional information is available if you would like to learn more about the new COI regulations, and how they differ from the prior requirements.

- View a side-by-side comparison table of the changes to the regulations
- Click here to read the final rule
- Click here for FAQ sheet issued by NIH
- Click here to read a message from the UC Davis Vice Chancellor for Research
- Click here to read a message from the President of the University of California System

UC Davis Financial Conflict of Interest in Research Resources

- Click here to access the UC Davis Conflict of Interest Webpage (http://research.ucdavis.edu/conflictofinterest)
- Click here to read the Draft UC Davis policy (hosted on the Academic Senate website)
- Click here to access the new PHS Online Disclosure (goes “live” August 24, 2012)
- Click here to enter the UC Learning Center (search for “COI-PHS” to launch the training)

Please contact Craig Allison, Research Compliance & Integrity (RCI) Director, at ccallison@ucdavis.edu if you have questions or need additional information.