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**To:** [or-spa@department-lists.uci.edu](mailto:or-spa@department-lists.uci.edu)  
**Subject:** [Sponsored Projects] New COI Disclosures Required Prior to PHSProposal Submission  
**Date:** Thursday, August 23, 2012 6:35:16 PM  
**Attachments:** [ATT2335719.txt](#)  
**Importance:** High

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Dear Colleagues:

On August 24, 2012, the revised Public Health Service (PHS) regulations regarding financial conflict of interest (FCOI) will take effect.

UCI and its employees are required to comply with these regulations because our campus applies for and receives research support from PHS agencies (directly and through subawards to UCI). Research support includes any activity for which research funding is available from a PHS agency through a grant (e.g., research grant, career development award, center grant, individual fellowship award, institutional training grant, program project, etc.), cooperative agreement or contract. In addition, these regulations apply to those [sponsors adopting the PHS regulations](#).

Changes reflected in the revised PHS regulations include the following:

- Lower disclosure thresholds – \$5,000 for publicly traded entities and \$0 for equity interests in non-publicly traded entities;
- Investigator disclosure regarding their Significant Financial Interests (SFI) related to their institutional responsibilities – not just those related to the specific research project in question;
- Disclosure of all sponsored and reimbursed travel – reimbursements or travel sponsored by educational and governmental institutions are exempted;
- Investigators must disclose new SFIs (including sponsored or reimbursed travel) within thirty (30) days of discovering or acquiring a new SFI; and
- Mandatory Investigator training regarding the PHS regulations and UCI's policy prior to engaging in the funded research.

The Vice Chancellor for Research (VCR) has issued several announcements to the campus (including messages directed toward UCI faculty, Deans, Directors, Officers and Administrators) regarding the implementation of the revised PHS regulations, the mandatory training of Investigators and UCI's obligation to comply with the regulations. In those announcements, he alerted the campus to potential delays that could result from less-than-timely compliance regarding disclosure of SFIs and completion of the mandated training for Investigators.

It is important to remember that the revised regulations require disclosure of SFIs no later than at the time of application for the funded research. As a result, the Office of Research (OR) cannot submit proposals to PHS or sponsors adopting the PHS regulations until all required disclosures have been received. Likewise, OR cannot release awards from PHS or sponsors adopting the PHS regulations until all Investigators have completed the mandated training. The timing of disclosure submission and training requirement also applies to subrecipient Investigators when the subrecipient organization will be relying on UCI's PHS FCOI policy and independent consultants if their role on the project satisfies the definition of Investigator. It is important to understand that the regulations define Investigator to mean the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS (or sponsors adopting the PHS regulations), or proposed for such funding.

The UC Office of the President has prepared an on-line course for Investigators called, "Compliance & Conflict of Interest for Researchers Briefing" that is available through the [UC Learning Center](#). This training must be completed by Investigators to satisfy the mandatory training requirement. While this information has already been shared broadly, I encourage all units to remind their Investigators about the course and their responsibility for completing the training.

To help inform administrative staff about the revised regulations and how staff can play an important role in helping to promote compliance, OR has developed a PHS FCOI traveling workshop. The workshop is approximately one hour in length and is designed to help staff understand the new requirements and the new processes, procedures and forms that UCI will use to facilitate compliance. Most importantly, the workshop is designed to come to you to minimize time away from the office while maximizing the opportunity for staff to attend the workshop. Staff from OR have already reached out to UCI's schools and research units to schedule this workshop. It will continued to be offered through September 28 to help staff prepare for the October 5th NIH proposal application deadline.

Additional information regarding the PHS regulations may be found on the [OR Conflict of Interest webpage](#) and UCI's policy implementing the PHS regulations may be found on the [OR Research Policy Library webpage](#). If you have any questions regarding the revised regulations, please contact me at [bruce.morgan@uci.edu](mailto:bruce.morgan@uci.edu) or at (949) 824-5677 or Grace Park, Conflict of Interest Administrator at [parkgj@uci.edu](mailto:parkgj@uci.edu) or at (949) 824-7218.

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