

PHS Financial Conflict of Interest (FCOI) Requirements for UC San Diego Investigators with Subrecipients

PHS is changing its financial conflict of interest (FCOI) rules effective August 24, 2012, and 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.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the University are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that complies with the PHS regulations, they must comply with the University's policies and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards.

Subawards issued by the University will ask the subrecipient institution to certify that its policy is in compliance with PHS conflict of interest regulations, and unless the subrecipient does not have a PHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending the University notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

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.

FEDERAL DEMONSTRATION PARTNERSHIP (FDP) RESOURCES FOR SUBRECIPIENTS

CLEARINGHOUSE

- The Federal Demonstration Partnership (FDP) recently announced the availability of a Clearinghouse of institutions and entities that have attested that they are or will be compliant with the updated PHS FCOI Regulations as of August 24, 2012.
- The purpose of this list is to allow institutions to quickly verify that their subrecipients will be compliant with the updated PHS FCOI policy requirements.
- Although this list is hosted by FDP, it is not limited to FDP member institutions. FDP has invited authorized organizational representatives of non-member FDP institutions and other entities to now enroll their institution at:
 - http://sites.nationalacademies.org/PGA/fdp/PGA_070596.

SAMPLE POLICY

- FDP has provided a sample policy for Subrecipient Organizations that currently do not have a PHS FCOI Compliant policy. This can be found at: http://sites.nationalacademies.org/PGA/fdp/PGA_061001
- Subrecipients who currently do not have a PHS FCOI Compliant policy are strongly encouraged to adopt their own PHS FCOI Compliant policy in order to reduce the administrative burden for Investigators and the Organization, and also to eliminate any possible delays in the issuance of PHS Subaward funding.

How Will These Changes Affect You?

These are the changes that will affect all UC San Diego's subawards with a Notice of Award on or after August 24, 2012

At Time of Proposal Submission

Subrecipients Listed on the FDP Clearinghouse of PHS FCOI Compliant Institutions

No further action is required.

Subrecipients NOT Listed on the FDP Clearinghouse of PHS FCOI Compliant Institutions:

1. The **Subrecipient Certification Form** must be completed.
2. The Subrecipient Authorized Organizational Official must certify whether they currently have a PHS FCOI compliant policy in place.
3. If the Subrecipient Organization does **NOT** have a PHS compliant Policy, the organization has two options:
 - a. Subrecipient can certify that the organization intends to have a PHS compliant policy in place at the time of award. *The FDP has provided a sample policy (please see "Available Resources" below) that Subrecipients can use to develop a PHS-compliant policy,*
 - b. OR the Subrecipient Organization can certify that it intends to abide by the University of California's PHS FCOI policy.
 - i. If the Subrecipient Organization intends to abide by UC policy, each Investigator must:
 1. Complete and submit the UC San Diego PHS COI Disclosure Form for Subrecipients to the COI Office
 2. Complete the UC PHS COI training, which is available on the UC San Diego COI website.

When Just In Time (JIT) or Notice of Award Notification is Received

Subrecipients Listed on the FDP Clearinghouse of PHS FCOI Compliant Institutions

1. The Subrecipient Organization must re-certify that it has a PHS FCOI Compliant Policy by completing the **Subrecipient Commitment Form** and return it to the Business Contracts Office.
2. If any of the Subrecipient Investigators have any conflicts requiring management, this information must be submitted to the UC San Diego Conflict of Interest Office to report to the PHS agency.

Subrecipients NOT Listed on the FDP Clearinghouse of PHS FCOI Compliant Institutions and are using the UC PHS FCOI Policy:

If any of the Subrecipient Investigators have answered "Yes" to any of the questions on the **UC San Diego PHS Financial Disclosure for Subrecipients** form, the UC San Diego COI Office must complete its review and if necessary, create a conflict management plan **PRIOR** to the issuance of the subaward contract.

Ongoing Compliance for Subrecipients

- Subrecipient organizations must disclose to the UC San Diego Conflict of Interest Office any conflicts of interest that arise and are required to be managed during the life of the award.
- Subrecipient investigators will be asked to certify annually whether there have been any status changes to any identified financial conflict of interests.
- Subrecipient Investigators will be required to renew their training every four years.

Available Resources

UC San Diego Conflict of Interest Office
<http://coi.ucsd.edu> or info@coi.ucsd.edu

UC San Diego Guidance for Subawards
<http://blink.ucsd.edu/buy-pay/contract-svcs/subcontract-subaward/index.html>

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

NIH Resources
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>