What is the purpose of this regulation?
The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Promoting Objectivity in Research or Financial Conflict of Interest (FCOI) regulation. (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

The regulations are not intended to inhibit relationships with industry and commercialization of technology. To promote objectivity in research, some relationships need to be disclosed and research conducted in such a way as to insure that financial interest does not affect the conduct of the research. Identification of a financial interest is not evidence of misconduct or bias. Disclosure creates the opportunity to manage, reduce, or eliminate even the appearance of bias.

What is the Public Health Service?
PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

When do the revised regulations go into effect?
The Public Health Service (PHS) initially issued conflict of interest regulations in 1995. They were recently revised in some important ways. The revised PHS regulations go into effect on August 24, 2012.

What is the most significant difference between the 1995 regulation and the 2011 revised regulation?
The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

- Definition of Significant Financial Interest
- Extent of Investigators' disclosure of information to Institutions regarding their Significant Financial Interests;
- Institutions’ management of identified Financial Conflicts of Interest
- Information reported to the PHS funding component (e.g., NIH);
- Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel); and
- Investigator training.

What am I required to disclose?
Investigators are expected to disclose all Significant Financial Interests.

Under the new regulations, as implemented by the University, who is an Investigator:
Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or
proposed for such funding, which may include, for example, collaborators or consultants.

All PHS Investigators should review the UC Policy: Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards -

Under the new regulations, as implemented by the University, what are institutional responsibilities?
Institutional Responsibilities means teaching/education, research, outreach, clinical service, and University and public service performed on behalf of the University of California which are within the course and scope of the Investigator’s University of California employment/appointment.

What’s a significant financial interest?
Under the new PHS rules means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse or registered domestic partner and dependent children, unless noted otherwise below) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

1. For a publicly traded entity
   The value of any remuneration received from the entity in the twelve months preceding the disclosure which when added to the value of any equity interest in the entity as of the date of disclosure, exceeds $5,000.

2. For a non-publicly traded entity
   Remuneration received from the entity during the twelve months preceding the disclosure that exceeds $5,000, or when the Investigator holds any equity interest in the entity.
   - Remuneration includes salary (other than salary provided by the University of California) and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
   - Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

3. Intellectual Property Rights
   Any income from intellectual property (i.e. copyrights or patents) that is not owned by the Regents of the University of California that exceeds $5,000 during the previous twelve months.

4. Travel
   Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities except for travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching
hospital, a medical center, or a research institute that is affiliated with an Institution of higher education (for the Investigator only).

Example: Travel reimbursement to attend an American Heart Association grant review panel or to a clinical trial investigator’s meeting must be disclosed.

Do I need to disclose all financial interests?

No, only those of yours (and your spouse, registered domestic partner and/or dependent children) that reasonably appears to be related to your institutional responsibilities and meet the threshold. For example, an investment in automotive company would only need to be disclosed if your work is related to automobiles such as the health effects of pollution or safety of automobiles.

When do I need to disclose Significant Financial Interests?

1. PHS Investigators are required to disclose to their campus all Significant Financial Interests no later than at the time of the application for PHS funding.

   Additionally, Investigators have an ongoing duty throughout the period of the award to disclose their (and those of their spouses or registered domestic partners, and dependent children) Significant Financial Interests according to the following timelines:

2. Within thirty days of discovering or acquiring any new Significant Financial Interest; and

   a. At least annually throughout the period of the award.

   Please note: this annual disclosure is a new requirement imposed by PHS; the University is trying to develop systems and guidance to make it as simple as possible for Investigators and the University to fulfill their responsibilities.

3. Before joining an on-going PHS-funded research project, new Investigators must also complete a disclosure of Significant Financial Interests.

As referenced in the 2011 revised regulation, who are the “senior/key personnel” in NIH-funded research?

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

I am a post-doctoral fellow receiving funding from the NIH. Does this regulation apply to me?

Yes. If you meet the definition of an “Investigator,” the PHS regulation applies to you.
I am a graduate student working on research funded by the NIH. Am I subject to the requirements of the Financial Conflict of Interest regulation?
Yes. If you meet the definition of an “Investigator,” the PHS regulation applies to you.

Does the regulation apply to any other agency or sponsor.
Yes. The regulation also applies to organizations that have adopted (or adopt in the future) PHS COI regulations such as American Heart Association, American Cancer, Susan G. Komen Foundation, and Alliance for Lupus Research.

Does the regulation apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)?
Yes. The 2011 revised regulation is applicable to each Institution that applies for or receives NIH funding for research through grants or cooperative agreements and, through the implementation of the regulation by each Institution, to each Investigator planning to participate in, or participating in, such research. A subrecipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the NIH-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c).