Revised Public Health Service Regulations (Highlights)

- Intended to increase accountability, add transparency, enhance regulatory compliance and effective management of financial conflicts of interest and strengthen governmental compliance oversight
Revised Public Health Service Regulations (Highlights)

- Increases disclosure, review and reporting requirements
- Adds a education/training requirement
- Adds a new public accessibility requirement
- Adds new monitoring requirements
Conflicts of Interest in Research

- **Current federal regulations (PHS)** require that investigators disclose significant financial interests that would *reasonably appear to be affected by the research for which support is sought or in entities that would reasonably appear to be affected by that research.*
Conflicts of Interest in Research

• Revised PHS regulation requires that investigators disclose significant financial interests related to their institutional responsibilities
Significant Financial Interests under the revised PHS regulations

- Anything of monetary value related to the investigator’s institutional responsibilities including but not limited to:
  - Salary or other payment for services and the value of any equity in a publicly traded entity >$5,000
  - Salary or other payment for services >$5,000 or any equity in a privately held entity
  - Intellectual property rights (e.g., patents, copyrights and royalties not paid by UC) upon receipt of income related to such rights (of any $ value)
  - Travel paid for, or reimbursed by, an outside entity (of any $ value)
Institutional Responsibilities

- Draft UC definition

“For the purposes of this policy, the term institutional responsibilities is defined as teaching/education, research, outreach, clinical service, and University and public service, on behalf of UC[LA], and directly related to those credentials, expertise and achievements upon which the Investigator’s UCLA position is based.”
Examples of Activities related to Institutional Responsibilities

- **Income or honoraria** received for activities such as providing expert testimony or consulting services, serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization, accepting a position as a salaried employee outside the University.

- **Stock or stock options** in a company developing, manufacturing or selling products or providing services used in an Investigator’s clinical practice, teaching, research, administrative or committee responsibilities;

- **Receipt of income from an organization other than The Regents** (such as royalties of licensing fees) for use or sale of patented or copyrighted intellectual property (e.g. software, textbooks, or other scholarly works); or

- **Travel** paid for or reimbursed by a professional society, a company for which the Investigator is consulting, or by any other for-profit or non-profit organization.
Review Process(es)

- *Revised* regulation require a two step review of activities related to an investigator’s institutional responsibilities to determine:
  
  1) if any disclosed significant financial interests would reasonably appear to be affected by the research for which support is sought or is in an entity whose financial interests would reasonably appear to be affected by that research, and then
  2) if any of those disclosed significant financial interests constitute a financial conflict of interest
Financial Conflict of Interest

“...a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.”

(Public Health Service regulations)
Revised Public Health Service Regulations: A Preview of Coming Attractions

- To be implemented by August 24, 2012
- Will be phased in with new PHS awards and new PHS proposals
- UC and UCLA drafting new policies and procedures specifically to address these regulations
- Just launched project to create an e-solution for disclosures.