Overview of Changes

- Effective date: August 24, 2012.
- Includes definitions of key terms (e.g., disclosure, financial conflict of interest [FCOI], financial interest, institutional responsibilities, investigator, manage, PI/PD, & research).
- Expanded definition of investigator that includes any other person, regardless of title or position, responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- Significant Financial Interest (SFI)
  - Minimum threshold of $5,000 generally applies to payments and/or equity interests.
  - Includes any equity interest in non-publicly traded entities ($0 threshold).
  - Includes reimbursed/sponsored travel for institutional responsibilities with some exceptions.
  - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
  - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Disclosure of all SFI related to the Investigator’s institutional responsibilities
  - Definition in policy of investigator’s institutional responsibilities.
  - Institutions are responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI).
- Subrecipients
  - More specific information about handling subrecipients vis-à-vis financial conflict of interest in research.
- Review of disclosures and management of conflicts
  - Specific timelines for reviews in specific circumstances (e.g., disclosure of new SFIs).
- Public notice
  - Before spending funds for PHS-supported research, Institution must make publicly available information on certain SFIs that the Institution has determined are related to the PHS-funded research and are FCOI.
- Investigator Training
  - FCOI training required for Investigators before engaging in PHS-funded research, every four years thereafter, and immediately under designated circumstances.
- Expanded reporting requirement to PHS Awarding Component when a FCOI is identified.
- Retrospective review
  - Institution is required to conduct a retrospective review in those cases of non-compliance with the regulation but is not required to report the review to the PHS Awarding Component except in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.