CHANGES IN FEDERAL REGULATION

Beginning August 24, 2012:

* Training in COI is federally required

* Threshold for a significant financial interest (SFI) has changed:
  ▪ PHS threshold is $5,000
  ▪ NSF threshold is $10,000
CHANGES IN FEDERAL REGULATION

Elements of financial calculation have changed

- For PHS—last 12 months only
  - Includes paid travel, service to professional societies
- For NSF—last 12 months and next 12 months
  - Excludes paid travel, service to/income from professional societies
CHANGES IN YALE POLICY AND PROCEDURE

* No change in annual disclosure requirement
* COI training is embedded in disclosure process
* Branched disclosure, based on funding
* If no federal funding, the threshold for an SFI is $10,000
IRB REVIEW AND CONSIDERATION

* Investigator informs IRB of protocol-specific conflicts
* IRB staff identify SFI (may be intellectual property)
* IRB determines whether or not conflict requires management for protection of human subjects
THE KEY

The charge to the IRB remains the same:

* the protection of subjects
* the integrity of the study data
FOR FULL UNIVERSITY COI INFORMATION

See the COI website:
http://coioffice.yale.edu/