NIH Conflict of Interest Rule and diSClose

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Major Changes in HHS COI Rule – 8/24/12

• **NEW** Requires annual disclosure of all significant financial interests related to any professional responsibilities on behalf of the institution (research, clinical care, instruction, service or committee work) regardless if there is a COI.
  – Disclosure must be updated to reflect new entities within 30 days.
  **BEFORE** Only COIs had to be disclosed.

• **NEW** Requires new HHS investigator training in COI, and repeated training at least every 4 years.
  **BEFORE** No mandatory training requirement.

• **NEW** Financial interest thresholds, public accessibility requirements and increased reporting requirements to HHS
Annual Disclosure Requirement

• Required for all HHS Investigators
  – An “Investigator” is the PI, co-PI, contact PI, or co-I. Other persons may be an investigator if they have independent responsibility for some aspect of the design, conduct, or reporting of research.

• Applies to those proposing for or with existing HHS-supported research

• Must be done before submitting a proposal for HHS funding
• May lead to additional types of disclosure such as a Conflict of Interest in Research (COI)
  – COI is a situation where financial considerations compromise, or have the appearance of compromising, an individual’s professional judgment in proposing, conducting, supervising or reporting research.

• Annual disclosure is required even if an investigator has no financial interests to disclose or the financial interests don’t lead to a COI
diSClose

• USC is developing diSClose – a “one-stop” electronic system to meet all disclosure requirements
  – NIH annual
  – COI in Research
  – RWI
  – COI and Ethics (purchasing or personnel conflicts)

• System currently in user testing
  – Expected July 16th rollout for NIH annual to meet 8/24 deadline
  – RWI and COI and Ethics rollout to follow NIH implementation
Questions?

NIH website (links to new rule and FAQs):
http://grants.nih.gov/grants/policy/coi/

Office of Compliance website:
http://ooc.usc.edu/conflict-interest

For training schedule see Research Compliance
Newsletter to follow

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