

# NIH Conflict of Interest Rule and diSClose

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

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- **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



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- 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

# Annual Disclosure Requirement (cont.)



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- 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

- 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 16<sup>th</sup> rollout for NIH annual to meet 8/24 deadline
  - RWI and COI and Ethics rollout to follow NIH implementation

# Questions?



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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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