HHS Annual Disclosure and Conflict of Interest Update

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What is the HHS COI Rule?

- 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.

- Requires new **HHS investigator training** in COI, and repeated training at least every 4 years.

- **Went into effect 8/24/12**
Who needs to complete an annual HHS disclosure?

• 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
When does it need to done?

For investigators with existing HHS funding:
• Must disclose annually
• Any NEW financial interests must be updated within 30 days

For first time HHS investigators:
• Must disclose and complete training prior to proposal submission
2014 Annual HHS disclosure schedule

Timeline for 2014

– 6/1/2014 – 2014 annual disclosure period opens in diSClose
– 7/31/2014 – 2014 annual HHS disclosures due
– 8/1/2014 – relevant Deans notified
– 8/24/2014 – HHS accounts frozen for any investigator not in compliance

Last year we had 759 disclosures completed by the deadline. Of those, over 60% had no outside financial interests to disclose.
How to disclose?

• diSClose – a “one-stop” electronic system to meet all disclosure requirements

https://disclose.usc.edu

– HHS annual
– COI in Research
– RWI
– COI and Ethics (purchasing or personnel conflicts)
Conflicts of Interest in Research

• COI in Research 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.

• An HHS annual disclosure can lead to a COI in Research disclosure in diSClose if the discloser is involved in research related to a financial interest.

• COI in Research applies to all researchers, regardless of funding.
Discussion of COI Scenarios

Scenario 1 – Dr. Tammy Trojan and Microchip, Inc.

Scenario 2 – Dr. Tommy Trojan and Trojan, Inc.
1.0 * Does this entity sponsor your research or that of your close relation?
Yes  No  Clear

2.0 * Has USC issued or does USC have an existing subaward with this entity to sponsor your research or that of your Close Relation?
Yes  No  Clear

3.0 * Are or will you be using any of the entity's products or materials (e.g. drugs, devices, compounds, specimens, intellectual property) in your research?
Yes  No  Clear
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

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