

HHS Annual Disclosure and Conflict of Interest Update

Ben Bell

Manager, Research Compliance

What is the HHS COI Rule?



Fight On

- 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?



Fight On

- 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 be done?



Fight On

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

Fight On

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?

Fight On

- 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



Fight On

- 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



Fight On

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

Scenario 2 – Dr. Tommy Trojan and Trojan, Inc.

How diSClose identifies a COI in Research

Fight On

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?



Fight On

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>

Benjamin Bell (bbell@ooc.usc.edu)

Manager, Research Administration Compliance

Tel. (213) 740-8258