

# Training on NIH Conflict of Interest Rule and Introduction to diSClose

Dan Shapiro

Director, Research Compliance

Ben Bell

Manager, Research Compliance

Office of Compliance



A Conflict of Interest in Research (COI) is a situation where financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research.

*"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process." — Dr. Francis Collins, Director, NIH*

# Timeline – Revisions to NIH Conflict of Interest Regulations



Fight On

**May, 2009:** NIH issues an Advance Notice of Proposed Rule Making (ANPR), proposing to overhaul 1995 federal regulation governing the identification, disclosure, and management of financial conflicts of interest (FCOI) related to research (42 CFR Part 50)

**May, 2010:** NIH issues its Proposed Rule, incorporating feedback from research community.

**November, 2010:** Research community awaits the issuance of the Final Rule.

**June, 2011:** OMB announces that review of rule is delayed indefinitely

**August 25, 2011:** New rule announced

**August 24, 2012:** New rule goes into effect

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

Fight On

- **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** Institution has larger role in COI determination.
  - **BEFORE** Investigator initiated COI disclosure.
- **NEW** COI information related to PHS funding must be made accessible to the public, either by request or through a publicly available website.
  - **BEFORE** No requirement.

# Major Changes (cont.)



Fight On

- **NEW** Requires NIH investigator training in COI at least once every 4 years.
  - **BEFORE** No mandatory training requirement.
- **NEW** Details on COIs related to PHS funding must be reported to sponsor and updated annually.
  - **BEFORE** Only the existence of a COI was reported.
- **NEW** Reporting threshold lowered to \$5,000 for payments for service.
  - **BEFORE** \$10,000 threshold.

- **NEW** If an investigator fails to disclose or update a conflict related to HHS research in a timely fashion, or to comply with the management plan, USC must conduct a retrospective review to assess research bias.
  - **BEFORE** No such requirement.
- **NEW** If bias is found, USC must document the review and submit a mitigation plan to the sponsor.
  - **BEFORE** No such requirement.

# Effects on USC

Fight On

- Annual disclosure will be required from all investigators with current or proposed NIH research.
- Projected increase in COIs that need to be managed and monitored.
- USC is offering live training and an on-line course from CITI to meet NIH training requirement.
- Greater institutional responsibility for oversight of all outside activity of an investigator. Increased administrative burden on CIRC and administrative units.
- New COI in Research policy will be issued to reflect the changes in the rule on 8.24.12.

# Definitions and Key Terms



Fight On

- **Investigator** - is the principal investigator, co-principal investigator, contact principal investigator, or co-investigator. Other persons may be an investigator, but only if they have independent responsibility for some aspect of the design, conduct, or reporting of research.
- **Close Relation** - the spouse, domestic partner, or dependent child of an Investigator or Research Personnel.



- **Financial Interest thresholds:**

1. Any equity in a non-publicly traded entity
2. Equity in a publicly traded entity of \$5,000 or more
3. Payments for services from either entity type of \$5,000 or more in the last 12 months
4. Any combination of 2 and 3 of \$5,000 or more
5. IP rights (excluding royalty payments from USC)
6. Any reimbursed or sponsored travel (except from excluded sources)

# Changes in USC Policy



Fight On

- Management roles must be disclosed
- Payments for services during the last 12 months and anticipated payments over the next 12 months equal to or greater than \$5,000 must be disclosed
- Simplified administrative procedures for managing more routine conflicts, meaning that committee review is not required in all cases
- Prohibition on engaging in paid speaker's bureaus for any company that has sponsored the Investigator's research



- “Significant Conflict” thresholds raised
  - Equity interests in privately-held entities in a research sponsor now only applies to the principal investigator, rather than to all investigators
  - Equity interest exceeds 10% of company valuation for non-human subjects research (prior threshold was any equity above 0%)
  - Threshold for “significant conflicts” associated with provision of consulting services in connection with human subjects research raised from \$10,000 to \$25,000

# Any good news?

Fight On

- USC has developed 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 will be available for annual disclosures on **July 31, 2012.**
- URL: <http://disclose.usc.edu>

- USC policy requires disclosure to COI in Research Committee.
- Committee makes recommendation to allow or disallow the activity to the VP of Research.
- If allowed, activity is subject to a management plan which must be followed and annual or semi-annual monitoring by Research Compliance.

# Summary



Fight On

- USC requires all investigators seeking or with DHHS research support to submit an annual disclosure of all outside financial relationships related to the investigator's institutional responsibilities, regardless of whether the relationship creates a potential conflict of interest.
- Annual disclosures must be updated to reflect new relationships within 30 days.
- If any relationships are related to research, and meet threshold requirements, a conflict of interest in research disclosure along with a proposed management plan must be submitted.
- Regardless of sponsor, all Investigators and Research Personnel must disclose potential or actual conflicts of interest at the time of proposal submission.

# Summary (cont.)



Fight On

- DHHS proposals may not be submitted unless each investigator has a current annual disclosure in diSClose.
- In the event of a potential conflict of research, research cannot begin and the account cannot be established before the conflict of interest disclosure is completed and reviewed.
- USC policy requires disclosure of actual activity in the prior 12 months as well as expected activity in the next 12 months.
- Potential conflicts of interest and management plans are reviewed by the CIRC and a final determination is made by the Vice President of Research or his or her designee.

# 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>

**Daniel Shapiro ([dshapiro@ooc.usc.edu](mailto:dshapiro@ooc.usc.edu))**

**Benjamin Bell ([bbell@ooc.usc.edu](mailto:bbell@ooc.usc.edu))**

Tel. (213) 740-8258