The University of North Carolina at Chapel Hill

Gillings School of Global Public Health

Conflict of Interest: Research and Summary of Federal Regulations

Joy Bryde, MSW
Conflict of Interest Officer
Asst. Director, Research Compliance Program
Who is Covered by the Policy on Individual Conflicts of Interest (COI) and Commitment?

Current Policy applies to all:

• University employees,
• students and
• trainees

in their performance of the teaching, research, public service, administration and business operations of the University, and in this context the individual may be referred to as a “Covered Individual”.

Eights sections for Conflict of Interest, including Research
What is a COI?

Conflict of interest is a situation in which financial or other personal considerations:

• may compromise,
• may involve the potential for compromising, or
• may have the appearance of compromising

a Covered Individual’s objectivity in meeting University duties or responsibilities, including research activities.

UNC Board of Governors Policy Manual
What is a FCOI?

Financial Conflict of Interest means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.
Why the Conflict of Interest (COI) Process?

• Comply with UNC BOG policy and Federal requirements (funding, human subjects, conflict of interest, etc.)

  DHHS 42 CFR Part 50, 45 CFR Part 94 effective 08/24/2012

• Maintain academic mission and integrity

• Honor the student/trainee experience

And most importantly

• Protect the credibility of the work that an individual is doing whether it is research or administrative

Mantra: Disclose and Manage
Summary of Regulatory/Policy Changes

Key Changes – Individual

• Mandatory COI training: every 4 years for all investigators (new) – UNC CH all individuals doing research
• Relatedness: institution determines if a disclosed financial interest is related to the employee’s institutional responsibilities (new- change from study responsibilities only)
• NIH definition for disclosure: Threshold lowered (to $5K), includes any equity, and scope of outside compensation is broadened (includes private non-profits)
  
   **NOTE: UNC-CH definition for disclosure: any $ value, of all relationships, even uncompensated**

• Disclosure for financial interests in the previous 12 months (new) UNC includes 12 months upcoming
• Disclosure of any changes in financial interest within 30 days (new)
Summary of Regulatory/Policy Changes

Additional Requirements

Individuals  **UNC-CH PHS ONLY**

- Travel, reimbursed or covered, must be disclosed to institution *(new)* – some exclusions on source of sponsorship
- Disclosure for paid authorship compensation or royalties now includes textbooks *(new)*

Institutional  **UNC-CH PHS ONLY**

- Sub-recipients must provide assurance of their own COI policy or fall under UNC’s policy *(new)*
- Increased reporting requirements from institution to NIH *(significantly more information to NIH including entity, role, $, management details)*
- Public accessibility means the University must share certain limited information for PHS funded senior/key personnel with FCOIs through response to public written requests *(new)*
Websites

Activities, Interests and Relationships:

air.unc.edu

All disclosures, External Activities for Pay (items created after August 24, 2012)

COI Training: coi-training.unc.edu

Prior websites: coi.unc.edu epap.unc.edu (items created before August 24, 2012)
Contact Information

Joy M. Bryde, MSW
Conflict of Interest Officer, Asst. Director, Research Compliance
Mailing Address: Research Compliance Program, UNC-CH CB 9103
Physical Address: 137 E. Franklin St. Suite 501 BOAC
E-mail: jbryde@unc.edu
Phone: (919) 843-9953

Website: http://research.unc.edu/offices/research-compliance-program/index.htm
General Email for questions: coi@unc.edu

Websites: air.unc.edu (items created after August 24, 2012)
coi-training.unc.edu
coi.unc.edu epap.unc.edu (items created before August 24, 2012)
COI TRAVEL DISCLOSURE
DECISION TREE

START
Are you an investigator on a PHS* funded project?

Yes

Is the travel related to your institutional responsibilities (primary & secondary duties)?

Yes, it's a primary or secondary duty

Is the travel reimbursed or sponsored by one of the following:
1. The University
2. US Federal, state or Local Gov't
3. A US academic institution or research center

Yes

You do not have to complete a COI Travel Disclosure

No

No, it's an external professional activity for Part FDPAR

You do not have to complete a COI Travel Disclosure

No

You have to complete the COI Travel Disclosure form. Please go to AIR.UNC.EDU

*Public Health Service (PHS) means the section of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, and the National Institutes of Health.