The University of North Carolina at Chapel Hill

Conflict of Interest and Summary of Regulatory Changes

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Why the Conflict of Interest (COI) Process?

• Maintain academic mission and integrity
• Comply with UNC GA and Federal requirements (funding, human subjects, etc.)
• 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

As a reminder:
- Conflict does not equal guilty.
- A conflict of interest can exist even if no improper acts are a result.
- A conflict can be managed but it still exists and must be acknowledged.

Mantra: Disclose and Manage
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

an employee’s objectivity in meeting University duties or responsibilities, including research activities.

*Note: This conflict can arise from a single or dual relationship.*

UNC General Administration Policy Manual
External professional activities for pay (EPAP) means any activity that
1) is not included within one's University employment responsibilities;
2) is performed for any entity, public or private, other than the University employer;
3) is undertaken for compensation; and
4) is based upon the professional knowledge, experience and abilities of the EPA employee.

NOTE: Activities for pay not involving such professional knowledge, experience and abilities are not subject to the advance disclosure and approval under EPAP policy but may be subject to a conflict of commitment consideration.

submit to epap.unc.edu
EPAP versus COI

• EPAP employment or personal activities may or may not become a conflict of interest (COI).

• An individual can consult, own equity in a company, or sit on an advisory board (paid or personal activities) without creating a COI (single relationship). *CAVEAT: there are some single relationships which are COIs.*

• A COI can be created generally when the individual establishes a second relationship with the entity. Examples:
  
  ➢ being a researcher studying the entity’s products, technology or services
  ➢ being funded by the entity to do research
  ➢ making purchasing decisions involving the entity’s products
  ➢ being the recipient of a directed donation from the entity
  ➢ having a spouse with any such relationships
Financial Conflict of Interest
Regulatory Changes Overview

- First update since 1995 of the Public Health Service regulation for FCOI
- UNC General Administration has completed their review and finalized the UNC BOG draft policy (to be voted on by BOG June 2012)
- COI Advisory Committee composed of faculty (COI Chairs) and staff to be convened to review UNC-CH policy for alignment with Final Rule, UNC BOG policy and campus practices
- Certain decisions regarding policy have been made by the Chancellor
  - maintain single policy regardless of source of funding
  - $0 de minimis
  - travel, book and public accessibility required only for PHS funded investigators
- Institutions that apply for or receive funding from PHS must be in compliance by August 24, 2012 or the day policy posted on website
Summary of Regulatory Changes

Key Changes – Individual

• Requirement that institution determines if a disclosed financial interest is related to the employee’s institutional responsibilities (change from study responsibilities only)

• NIH definition: De minimis threshold for disclosure is lowered (to $5K), includes any equity, and scope of outside compensation subject to disclosure is broadened (now includes private non-profits)

  NOTE: UNC requires full disclosure, any $ value, of all relationships

• Disclosure for financial interests in the previous 12 months (new timetable)

• Travel, reimbursed or covered, must be disclosed to institution (new) – some exclusions on source of sponsorship

• Paid authorship, royalties, copyrights, textbooks, must be disclosed to institution (new)

• Mandatory training requirement every 4 years for investigators (new)

• Timely disclosure of any changes in significant financial interest must occur within 30 days (new)
Summary of Regulatory Changes

Key Changes – Institutional

• Requirement that institution determines if a disclosed financial interest is related to the employee’s institutional responsibilities (change from study responsibilities only)
• Tracking of travel and authorship disclosure information (new)
• External to UNC researchers, sub-recipients or independent contractors, must provide assurance of their own COI policy or fall under UNC’s policy (new)
• Creation of disclosure and training system accessible to UNC and external users (new)
• De minimis threshold for reporting to NIH to be consistent with institution’s policy (new)
• Increased reporting requirements from institution to NIH (significantly more information to NIH including entity, role, $, management details)
• Public accessibility of FCOI through website or written response to inquiries (new)
• Retrospective Reviews and Mitigation Reports for changes to disclosures reported after 30 day window (new)
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