

The University of North Carolina at Chapel Hill

Gillings School of Global Public Health Conflict of Interest: Research and Summary of Federal Regulations

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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

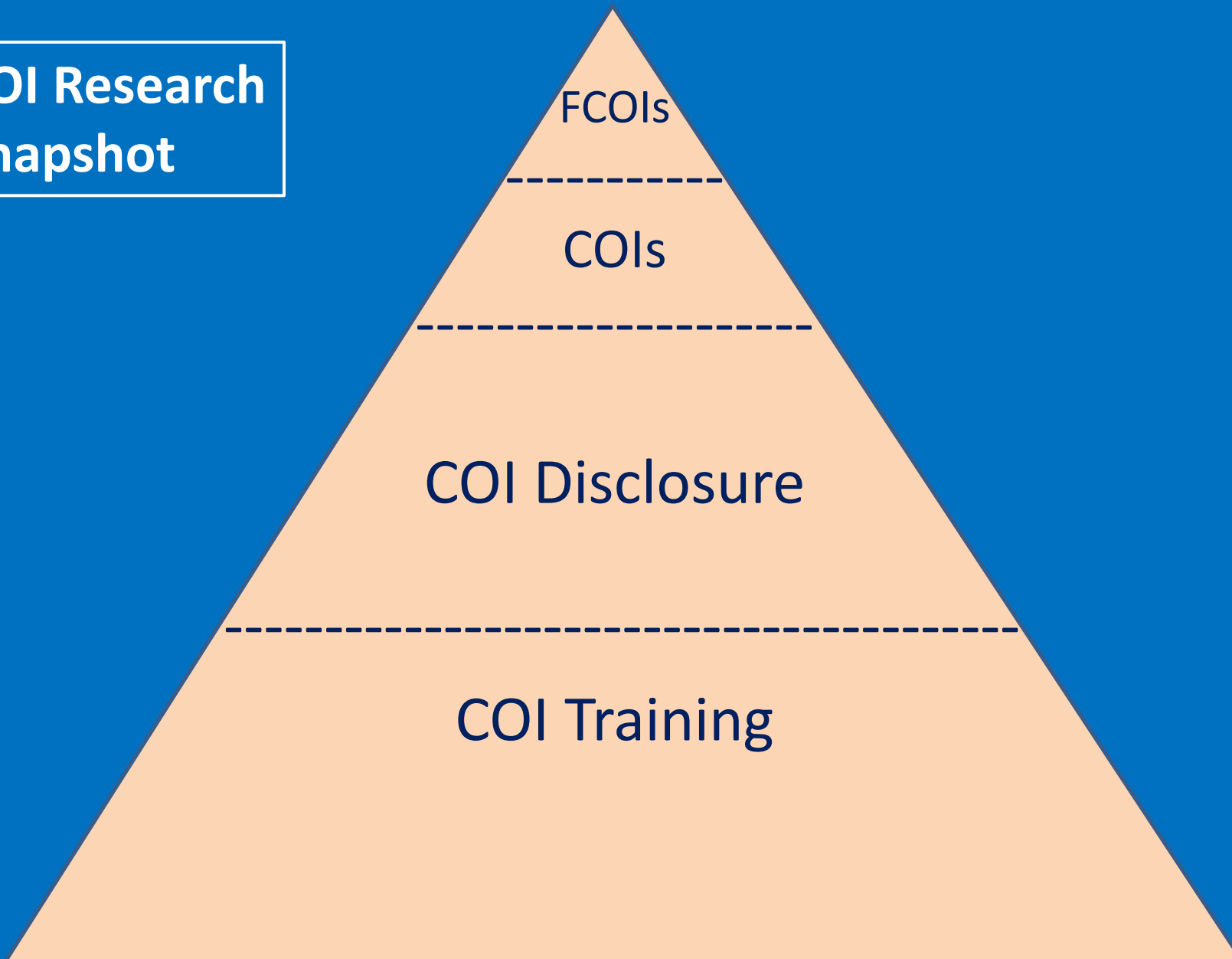
a Covered Individual's objectivity in meeting University duties or responsibilities, including research activities.

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.

**COI Research
Snapshot**



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)

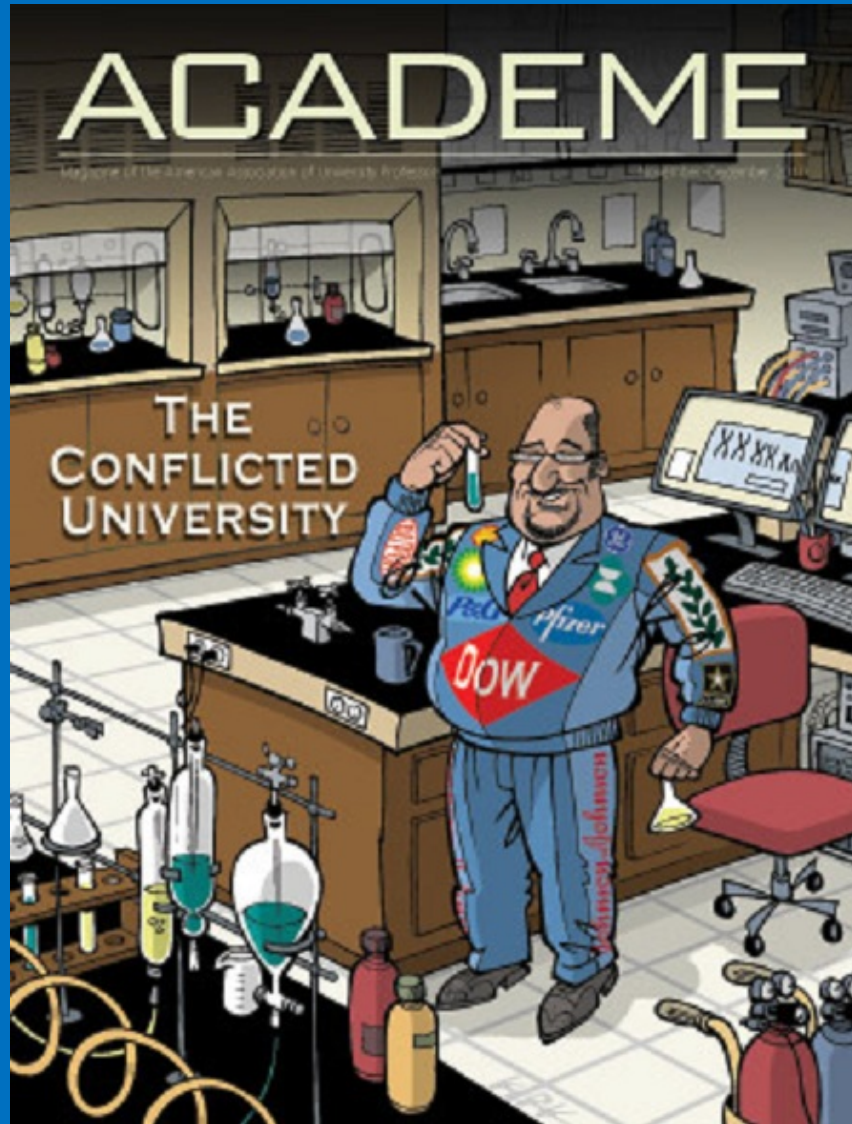
COI Training: coi-training.unc.edu

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

ACADEME

Magazine of the American Association of University Professors

THE CONFLICTED UNIVERSITY



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General Email for questions: coi@unc.edu

Websites: air.unc.edu (items created after August 24, 2012)

coi-training.unc.edu

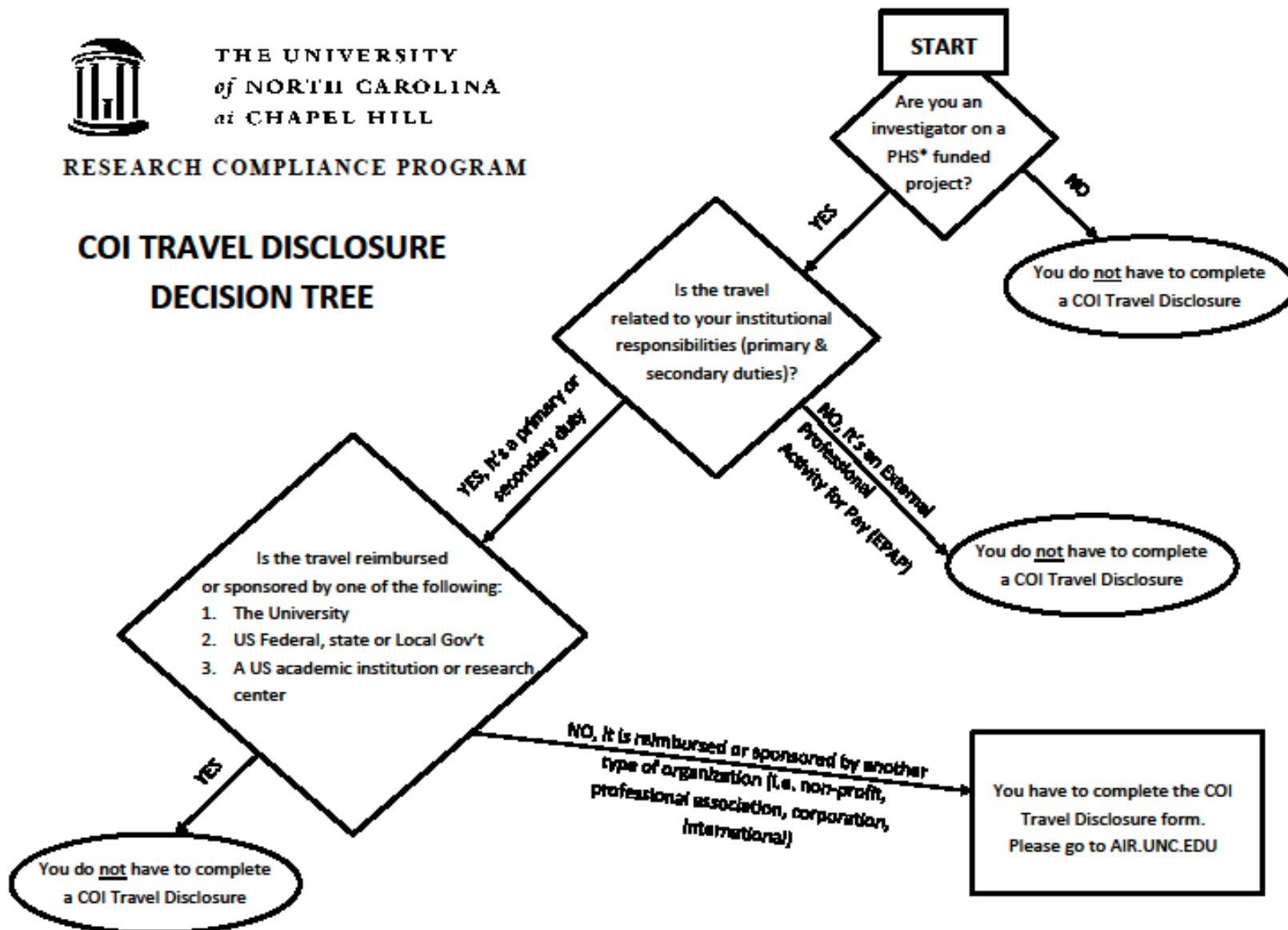
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of NORTH CAROLINA
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RESEARCH COMPLIANCE PROGRAM

COI TRAVEL DISCLOSURE
DECISION TREE



*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.