

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

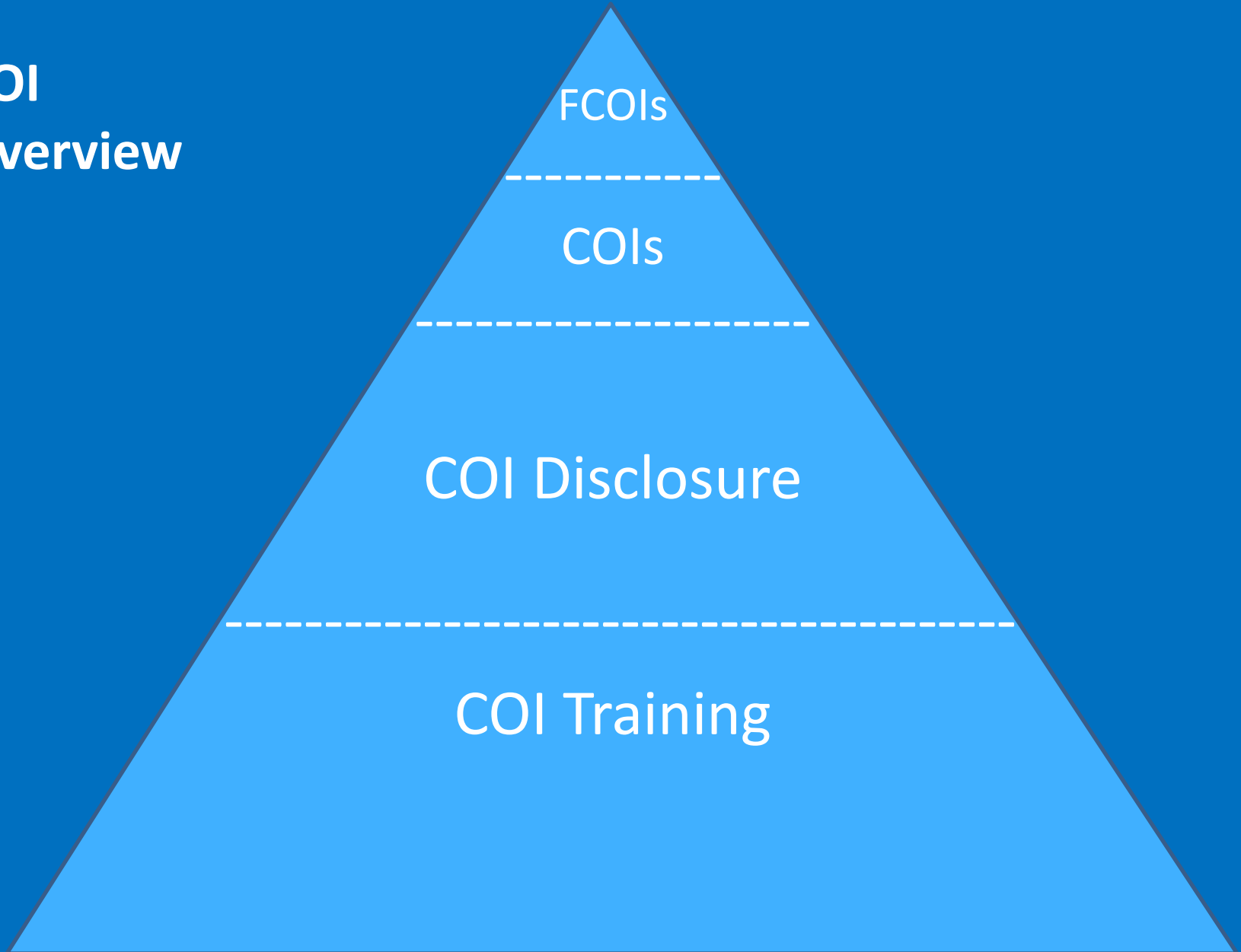
an employee's objectivity in meeting University duties or responsibilities, including research activities.

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

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 Overview



At UNC-Chapel Hill, Financial Interest Includes...

NOTE: Applies to individual or immediate family (spouse/household partner, dependent children) and received in the 12 months preceding or following disclosure:

- (1) Salary external to the University, royalties, consulting fees and honoraria
- (2) Equity interest held in publicly-traded or non-publicly traded entities
- (3) Intellectual Property rights and interests (including inventorship)
- (4) Gifts that have been made to the University for the direct benefit of the research or other professional activities of a Covered Individual

Financial Interest Does Not Include...

- 1) Salary from the University;
 - (2) Income from seminars, lectures, or teaching engagements sponsored by
 - (3) Income from service on advisory committees or review panels for
 - (4) Income from investment vehicles, such as mutual funds or blind trusts, where an individual or immediate family has no control over the selection of holdings.
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- US Federal, state, or local government agency,
 - a US institution of higher education,
 - a US academic teaching hospital,
 - a US medical center,
 - or a US research institution that is affiliated with a US institution of higher education

University Duties or aka Institutional Responsibilities

Primary Duties

- Teaching
- Scholarship
- Research
- Institutional Service
- Administrative duties
- Other assigned employment duties

Secondary Duties

- membership/service to professional associations
- membership on professional review or advisory panels
- presentation of lectures, papers, concerts or exhibits
- participation in seminars and conferences
- reviewing or editing scholarly publications and books without receipt of compensation
- service to accreditation bodies

NOTE: PER UNC BOG Policy, secondary duties may or may not entail the receipt of honoraria, remuneration or the reimbursement of expenses.

EPAP

(External Professional Activities for Pay)

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.

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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

Summary of Regulatory/Policy Changes

Key Changes – Individual

- Mandatory training requirement every 4 years for all investigators involved in research (new) – UNC CH all individuals doing research
- Requirement that institution determines if a disclosed financial interest is related to the employee's institutional responsibilities (change from study responsibilities only)
- NIH definition for disclosure: De minimis threshold is lowered (to \$5K), includes any equity, and scope of outside compensation subject to disclosure is broadened (now includes private non-profits)
NOTE: UNC-CH definition requires \$ value, of all relationships, even uncompensated
- Disclosure for financial interests in the previous 12 months (new) and following 12 months UNC-CH
- Timely disclosure of any changes in any financial interest must occur within 30 days (new)
- Paid authorship, royalties, copyrights, must be disclosed to institution regardless of source UNC-CH

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 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)
- 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)

Summary of Regulatory/Policy Changes

Key Changes – Institutional

- External to UNC researchers such as independent contractors must be assessed to determine if investigators and if yes, provide assurance of their own COI policy or fall under UNC's policy (new)
- Tracking of travel and authorship disclosure information (new)
- Creation of disclosure and training system accessible to UNC and external users (new)
- Increased reporting requirements from institution to NIH (significantly more information to NIH including entity, role, \$, management details)
- Retrospective Reviews and Mitigation Reports for changes to disclosures reported after 30 day window (new)

Contact Information

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