NOTES ON CONFLICT OF INTEREST

These notes on Conflict of Interest are based on the current University of North Carolina at Chapel Hill policy as well as anticipated changes with the upcoming implementation of the new Federal regulations on August 24, 2012.

COVERED INDIVIDUALS
The Individual Policy on Conflict of Interest and Commitment applies to:

- University employees
- students
- 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.”

In accordance with federal regulations, the interests of an immediate family member are considered the “same as” of the covered individual. A Covered Person’s immediate family is defined as a spouse and dependent children. For the purposes of the University Policy, an immediate family member includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations.

TERMS TO KNOW
Financial Interest: anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). Exceptions are mutual funds or blind trusts.

Disclosure: 1) to submit to the University the details of any potential conflicts of interests; 2) to share details of a conflict of interest with subjects, in presentations or publications as necessary.

DEFINITION OF A CONFLICT OF INTEREST
A conflict of interest relates to situations in which financial or other personal considerations, circumstances, or relationships:

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

a Covered Individual’s objectivity in fulfilling their University duties or responsibilities, including research, service and teaching activities and administrative duties.

The bias that such conflicts may impart can affect many University responsibilities, including:

- decisions about personnel
- the purchase of equipment and other supplies
- the selection of instructional materials for classroom use
- the collection, analysis and interpretation of data
- the sharing of research results, the choice of research protocols
• the use of statistical methods
• the mentoring or judgment of student work.

The above guidelines are used in the review of a disclosed potential conflict.

DEFINITION OF A FINANCIAL CONFLICT OF INTEREST
A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator’s Financial Interest is related to the person’s institutional duties and could directly and significantly affect the design, conduct or reporting of the research.

POLICY COMPARISON

Comparison of UNC-CH Policy with Federal COI Regulations

http://research.unc.edu/offices/research-compliance-program/index.htm

<table>
<thead>
<tr>
<th>Topic</th>
<th>UNC-CH Policy (Current)</th>
<th>1995 Regulations (Current)</th>
<th>2011 Final Rule (effective 8/24/2012)</th>
<th>UNC-CH Anticipated Policy (New)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Financial Interest (SFI) defined</td>
<td>FULL disclosure - all compensated and uncompensated relationships with any entity.</td>
<td>Compensation ≥ $10,000. Ownership interests ≥ 5% for non-publicly traded entities.</td>
<td>Compensation ≥ $5,000. Ownership interests &gt; 0% for non-publicly traded entities. Income from patents/copyrights.</td>
<td>FULL disclosure - all compensated (any dollar amount) and uncompensated relationships with any entity.</td>
</tr>
<tr>
<td>Which SFIs Need to Be Disclosed to University?</td>
<td>Investigator reports ANY financial interest to UNC.</td>
<td>Only those SFI an Investigator deems related to PHS funded research.</td>
<td>ALL SFI related to Investigator’s institutional responsibilities.</td>
<td>Investigator reports ANY financial interest to UNC.</td>
</tr>
<tr>
<td>Types of SFI excluded</td>
<td>Mutual funds and trusts</td>
<td>Mutual funds and trusts</td>
<td>Mutual funds and trusts- Investigator cannot directly control investment decisions.</td>
<td>Mutual funds and trusts- Investigator cannot directly control investment decisions.</td>
</tr>
<tr>
<td>Requirement</td>
<td>Requirement details</td>
<td>Disclose to Institution</td>
<td>New regulation will only apply to PHS funded investigators.</td>
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<tr>
<td>Travel*</td>
<td>Travel reimbursement is not mentioned explicitly in the regulations, but is not excluded from the SFI definition.</td>
<td>Disclose to Institution any reimbursed or sponsored travel related to Institutional duties.</td>
<td>EXCLUSIONS</td>
<td></td>
</tr>
<tr>
<td>Authorship*</td>
<td>Paid authorship is not mentioned explicitly in the regulations, but is not excluded from the SFI definition.</td>
<td>Disclose to Institution of any paid authorship activity, including textbooks, and resulting income.</td>
<td>New regulation will only apply to PHS funded investigators.</td>
<td></td>
</tr>
<tr>
<td>Including Textbooks</td>
<td>No requirement except to disclose royalty income.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Accessibility*</td>
<td>No requirement</td>
<td>FCOIs held by personnel listed on a public Web site OR written response to any requestor within 5 business days. [Name, research role, entity, nature of SFI, dollar range.]</td>
<td>New regulation will only apply to PHS funded investigators.</td>
<td></td>
</tr>
<tr>
<td>FCOI training</td>
<td>No requirement</td>
<td>Investigator must complete training prior to engaging in research and every four years thereafter.</td>
<td>All individuals must complete COI training &amp; every four years thereafter.</td>
<td></td>
</tr>
</tbody>
</table>

*Travel, Authorship, and Public Accessibility Requirements: At UNC-Chapel Hill these requirements will apply ONLY to investigators with PHS funding.
**Exclusions to Travel COI Disclosure:** travel does NOT need to be disclosed when the travel is reimbursed or sponsored by a Federal, state, or local government agency, OR Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education in the United States.

**WHAT IS THE COI PROCESS?**

Disclosure forms are created at specific events or should be started at particular times:

- Trigger events – created automatically by system upon submission into Ramses or IRBIS
- Annual – currently created and required for those people in administrative “influence” positions
  - NOTE: Will also be required for researchers beginning fall 2012
- Self-identified need to disclose (for Intellectual Property Licenses, gifts), initiated at coi.unc.edu website
- Federal regulation requires each Investigator to submit an updated disclosure of financial interest within 30 days of discovery or acquisition of a new financial interest.

**Trigger Events:**

Step 1: Individual Submission
Individuals receive email notification at time of PI certification for OSR proposal (IPF) or IRB application (IRBIS). Individual answers the questions on disclosure form. A person must Save, Submit, and Certify (three steps total) in order for disclosure to be received into the online COI system.

Step 2: System Assessment.
If no conflicts indicated, these disclosures are filtered out every 10 minutes and the IRBIS or Ramses systems are automatically updated.

If potential conflict is indicated, the form is triaged to particular screen in the online system where the form is reviewed by the COI team within the Research Compliance Program (RCP).

Every disclosure starts with this Administrative Review. Depending on the nature of the potential/ appearance of a conflict, the disclosure may go through additional reviews at the appropriate School Committee Level. Each disclosure is reviewed on a case by case basis.

**FAQ**

Q: Where can I go to see all of my personal COI Disclosures- incomplete or completed?
A: Any UNC person with an ONYEN/ password can log into coi.unc.edu at any time to view all of their disclosures; certified, in progress, or to be completed. After logging in, go to the left hand side of screen “My Dashboard”. Look for “My Disclosures”. Move throughout tabs to locate disclosures depending on their status: “Incomplete”, “Submitted”, “Re-opened”.

Q: Is travel sponsored or reimbursed from a non-governmental organization (within the US or outside the US), foreign Institution of higher education, or the government of another country required to be disclosed if I am a PHS funded investigator?
A: Yes. When the federal regulation refers to exclusions, the reference is for United States institutions of higher education or a federal, state or local government agency within the U.S. International governments or universities are not in the exclusion list. Non-profits, even those funded by the federal government, are not excluded.

ADDITIONAL CONSIDERATIONS

GIFTS
Gifts and donations that have been made to the University or to a University-affiliated foundation for the benefit of the professional activities of a specific faculty or staff member or student or trainee are considered to be a personal financial interest of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary. Such gifts and donations, where they coincide with University activities undertaken by the beneficiary that relate to the entity making the gift or donation, may create a conflict of interest, and they shall be reported by that individual for any other personal financial interest.

SUB-AWARDS

Federal regulations require that if the University carries out any PHS-funded research through sub grantees, contractors, or collaborators, the University must take reasonable steps to ensure that investigators working for such entities either comply with the University’s policy on conflict of interest or provide contractual assurances to the University that the sub grantee, contractor, or collaborator investigators are in compliance with the NIH’s regulations on conflict of interest in NIH funded research.

The University’s Office of Sponsored Research requires that sub recipients provide an indication during the application process of contractual assurance of their compliance with NIH’s policy on Conflict of Interest or the intent to comply with the University’s policy on conflict of interest.

If the sub-recipient provides assurance of their own policy, there is a contractual obligation which includes a requirement that the sub recipient report to the University’s Office of Sponsored Research the following information for any financial conflict of interest of sub recipient personnel: (a) sub recipient contract number (b) name of the sub recipient investigator with a financial conflict of interest (c) the method by which the conflict of interest has been addressed to protect the integrity of the NIH –sponsored project – e.g. managed, reduced or eliminated. The Office of Sponsored Research will forward a copy of each such sub recipient report, identified by NIH grant number, to the NIH with copy to the PI and the Conflict of Interest Officer.

If the sub recipients choose to comply with the University’s policy, then all individuals participating in the sub-contract must be named at the time of application and complete the necessary disclosure process and applicable training.