

NOTES ON CONFLICT OF INTEREST

These notes on Conflict of Interest are based on the current University of North Carolina at Charlotte policy, the implementation of a new electronic disclosure system (AIR), as well as recent changes resulting from the new PHS Federal regulations enacted on August 24, 2012.

COVERED INDIVIDUALS

University Policy 101.24, Conflicts of Interest and Commitment applies to:

- All Faculty (including part-time)
- EHRA Staff
- Designated SHRA Staff
- Anyone responsible for the Design, Conduct, or Reporting of research (not necessarily limited to UNC Charlotte employees) 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 Person.”

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.

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.

University Employment Responsibilities means both University Primary Duties and University Secondary Duties.

University Primary Duties means assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties. For any Covered Employee who is not an employee of the University (such as a subcontractor employee, collaborator, or consultant), the term “University Primary Duties” means those activities for which that person is responsible under the relevant Public Health Service-funded research project.

University Secondary Duties means professional affiliations and activities traditionally undertaken by Covered Persons outside of the immediate University employment context and include

- membership in and service to professional associations and learned societies;
- membership on professional review or advisory panels;
- presentation of lectures, papers, concerts or exhibits;
- participation in seminars and conferences;
- review or editing of scholarly publications and books; and
- service to accreditation bodies.

Secondary Duties need not entail the receipt of honoraria, remuneration or the reimbursement of expenses. University Secondary Duties demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and effective performance of the Covered Person's Primary University Duties or violate any University Policies. For any Covered Employee who is not an employee of the University (such as a subcontractor employee, collaborator, or consultant), the term "University Secondary Duties" means all of that person's activities other than the University Primary Duties that are directly related to those University Primary Duties.

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 Person'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.

Comparison of UNC-Charlotte Policy with Federal COI Regulations

Topic	1995 NSF Regulations	2011 PHS Final Rule	UNC-Charlotte Policy
Significant Financial Interest (SFI) defined	Compensation ≥ \$10,000. Ownership interests ≥ 5% for non-publicly traded entities.	Compensation ≥ \$5,000. Ownership interests > 0% for non-publicly traded entities Income from patents/copyrights. Compensation ≥ \$5,000.	FULL disclosure - all compensated (any dollar amount) <u>and</u> uncompensated relationships with any entity.
Which SFIs Need to Be Disclosed to University?	Only those SFI an Investigator deems related to NSF funded research.	ALL SFI related to Investigator's institutional responsibilities.	Investigator reports ANY financial interest related to their institutional responsibilities.
Types of SFI <u>excluded</u>	Mutual funds and trusts	Mutual funds and trusts- Investigator cannot directly control investment decisions	Mutual funds and trusts- Investigator cannot directly control investment decisions
Travel*	Travel reimbursement is not mentioned explicitly in the regulations, but is not excluded from the SFI definition	Disclose to Institution any reimbursed or sponsored travel, ≥ \$5,000, related to Institutional duties. <i>Exclusions listed below.</i>	New regulation will only apply to PHS funded investigators.

**Comparison of UNC-Charlotte Policy with Federal COI Regulations –
Continued**

Topic	1995 NSF Regulations	2011 PHS Final Rule	UNC-Charlotte Policy
Authorship Including Textbooks	Paid authorship is not mentioned explicitly in the regulations, but is not excluded from the SFI definition.	Disclose to Institution any paid authorship activity, including textbooks, and resulting income.	New regulation will apply to all Covered Persons.
Public Accessibility*	No requirement	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.]	New regulation will only apply to PHS funded investigators.
FCOI training	No requirement	Investigator must complete training prior to engaging in research and every four years thereafter.	All Investigators must complete COI training & every four years thereafter.

***Travel and Public Accessibility Requirements: At UNC-Charlotte 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. Travel that does not exceed the *de minimus* threshold of \$5,000 / year is also excluded from the disclosure requirement.

WHAT IS THE COI PROCESS?

All COI disclosures should be submitted online through the Activities, Interests, and Relationships (AIR) System: <https://uncc.myresearchonline.org/air/>

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

- Trigger events – created automatically by system upon submission of IPF into NORM
- Annual – Required for all Faculty and EHRA Staff.
- Self-Initiated – (for Intellectual Property Licenses, gifts, updating previous disclosure information, etc.), initiated using the AIR website
- Paid Authorship and Travel – only required for PHS funded projects, initiated using the AIR 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 Department Approval for NORM proposal (IPF). Individual answers the questions on disclosure form. A person must Save, then Submit and Certify in order for their disclosure to be received into the online COI system.

Step 2: System Assessment.

If no conflicts are indicated, these disclosures are filtered out every 10 minutes and the NORM system is automatically updated.

If a potential conflict is indicated, the disclosure form is administratively reviewed by the COI Manager.

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

Any UNC Charlotte person with a NinerNET ID/password can log into AIR 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”.

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 NSF or 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 collaborating investigators are in compliance with the relevant NSF or PHS regulations on conflict of interest in funded research.

The University's office of Research & Economic Development requires that sub recipients provide an indication during the application process of contractual assurance of their compliance with Federal policies 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 Research & Economic Development 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 PHS –sponsored project – e.g. managed, reduced or eliminated. The office of Research & Economic Development will forward a copy of each such sub recipient report, identified by grant number, to the PHS sponsor with a copy to the PI and the Conflict of Interest Manager.

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. If there are any changes in the list of participating personnel, the sub recipient is responsible for communicating these changes to the office of Research & Economic Development.