

FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

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OVERVIEW

- Office of Research Integrity
- Conflict of Interest – What is it??
 - Compliance at UNCG
- Federal Regulation
- How to Identify it?
 - Definitions
 - Significant Financial Interest & exclusions
- Investigator & Institutional Responsibilities
- NC Regulations



OFFICE OF RESEARCH INTEGRITY

Provides guidance & oversight to campus to ensure compliance with federal regulations:

- Human Subjects (IRB)
- Animal Subjects (IACUC)
- Biologicals on campus (IBC)
- Conflicts of Interest (COIC)
- Export Control



CONFLICT OF INTEREST COMPLIANCE PROGRAM



“An effective compliance program addresses the Government’s and research community’s **mutual goals of ensuring good stewardship** of Federal funds by eliminating erroneous or improper expenditure of Federal research funds, improving administration of grants (both from the Federal Government and from private sources), **and demonstrating to employees and the community at large the institution’s commitment to honest and responsible conduct.**”*

* Source – 70 Federal Register 71312 (Office of the Inspector General DHHS)

FEDERAL REGULATIONS

Rewritten in 2011 to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management and strengthen NIH's compliance oversight.

Public Health Service (PHS), Health and Human Services (HHS) & National Institute of Health (NIH):

- 42 CFR Part 50, Subpart F, (Grants & cooperative agreements)
- 45 CFR Part 94 (Contractors)

Went into effect in 2012

DEFINITIONS

- **Investigator** – project director or Principal Investigator
 - Any individual responsible for the design, conduct, or reporting of research
- **Financial Conflict of Interest (FCOI)** – a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. (\$5,000/year)
- **Financial interest** – anything of monetary value
 - Whether or not the value is related to research project at hand
 - Includes immediate family
- **Disclosure of significant financial interests** – disclosure by the investigator to the Institution.

SIGNIFICANT FINANCIAL INTEREST (SFI)

- **SFI** exists if the value of any remuneration received within a year > **\$5,000**, including:
 - External salary and payment for services
 - (consulting fees, honoraria, paid authorship);
 - Equity interest
 - (any stock, stock option, or other ownership interest in related or supporting entity)
 - Income related to intellectual property rights and interests
 - (e.g., patents, copyrights),
 - Reimbursed or sponsored travel related to their institutional responsibilities
 - does not apply to travel sponsored by Federal, state, or local government, institutions of higher education, teaching hospitals, medical centers, or a research institute that is affiliated with higher education.

SFI EXCLUSIONS

- Salary, royalties, or other remuneration paid by the University including:
 - intellectual property rights assigned to the Institution
 - agreements with investigators to share in royalties related to such rights;
 - ownership interest in the Institution held by the Investigator,
 - if the Institution is a commercial or for-profit organization;
 - income from investment vehicles, such as mutual funds and retirement accounts,
 - as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - income from seminars, lectures, teaching engagements, service on advisory committees or review panels
 - sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or an affiliated research institute;

INVESTIGATOR DISCLOSURE OF SFIs



- At time of Application:
 - If planning to participate in PHS/NIH-funded research, must disclose at time of application.
- Annually:
 - Submit an updated yearly disclosure of any SFIs (**or lack thereof**), per institutional policy.
- Within 30 days:
 - Those who are participating in the NIH-funded research must submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

INSTITUTIONAL RESPONSIBILITIES



- Establish Policy & Procedures
 - Make FCOI policy publicly available:
<https://coi.uncg.edu/>
- Maintenance of records,
 - Certify compliance
- Institutional Official:
 - Information & Training for Investigators
 - Help with disclosure of SFIs
- Management & Reporting of FCOIs
 - Management Plans must contain:
 - Role and principal duties of the conflicted investigator in the project,
 - Conditions of the management plan
 - How plan will safeguard objectivity
 - Confirmation of investigator's agreement
 - How plan will be monitored for compliance
 - Updated annually



NORTH CAROLINA REGULATIONS

CRIMINAL SELF DEALING

NC § G.S. 14-234



- It is a crime for public officials and employees to contract with the units of government they work for or represent. It is a misdemeanor for an employee who is involved in making or administering a contract to derive a direct benefit from that contract.
 - **The statute applies to any kind of contract.** The law applies to purchase orders; service contracts (including payment for using companies or facilities owned by a public official or employee); employment contracts; leases, sales and purchases of real and personal property; and any other type of contract through which the public official or employee, or their spouse, obtains any of the three types of direct benefit as defined in the statute.
 - **A violation of the statute is a Class I misdemeanor and renders the contract void.** Up to 120 days in jail and fines. Prosecutions under this statute are rare, but a violation definitely makes headlines. If the contract is void, the unit has no authority to expend funds under it.

GIFTS AND FAVORS

NC GS § 133-32 AND § 138A-32



- No contractor, subcontractor, or supplier who has a relationship with the university is allowed to make gifts or to give favors to any employee charged with the duty of:
 - Preparing plans, specifications, estimates; Awarding or administering contract; or Inspecting or supervising construction.
 - It shall also be unlawful for any officer or employee to willfully to receive or accept any such gift or favor
- A violation shall be a Class I misdemeanor.
- Gifts or favors made unlawful by this section are not allowed as a deduction for North Carolina taxes
- EXCLUDED:
 - Gifts and receipts of honorariums for participating in meetings
 - nonmonetary memento recognizing individual services
 - specialty advertising items or souvenirs of nominal value
 - meals furnished at banquets

QUESTIONS?

Websites:

<https://coi.uncg.edu/>

<https://integrity.uncg.edu/>

<https://exportcontrol.uncg.edu/>