

PROCEDURES FOR THE DISCLOSURE, REVIEW, AND MANAGEMENT OF ACTIVITIES INVOLVING POTENTIAL FINANCIAL CONFLICTS OF INTEREST

The University of North Carolina at Greensboro

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The Chancellor has designated that the Director of UNCG's Office of Research Integrity shall act as the senior UNCG official assigned with oversight of campus policies and procedures for reviewing and managing conflicts of interest involving all UNCG Faculty and EHRA Non-Faculty employees. The applicable policies, as adopted and as may be amended, are the UNCG Policy on Conflict of Interest and Commitment, and UNC 300.2.2, *Conflicts of Interest and Commitment*. All capitalized terms in these Guidelines that are not defined herein shall have the meaning set forth in the UNCG Conflict of Interest and Commitment Policy.

I. OVERVIEW

A. Core Concept

Financial Conflicts of Interest of concern to the University typically involve 3 parties with distinct interests:

1. A University employee, whose interests lie with both their commitment to the University (e.g., their professional roles, responsibilities, and reputation) and their private interests outside of the University (e.g., financial, social, reputational, relational);
2. The University, whose interests are in the fulfillment of its mission, the upholding of professional and ethical standards, the sustainment of financial viability, and the success of its employees and students; and
3. An entity outside of the University, typically a business but sometimes a non-profit, whose interests are usually wholly independent of the University's interests, and focused on the development of products or provision of services, often with financial gain as a primary goal.

Research and scholarship— the conduct or creation of, intellectual property resulting from, or expertise related to – is the most common element of University work in which conflicts of interest arise. Whether in the context of testing products or materials, developing instructional curricula, or utilizing expertise for roles in external organizations, a clear understanding of the different interests at hand, and the extent to which they are intertwined, is of utmost importance.

B. Categories of potential conflicts of interest per the University's Conflicts of Interest and Commitment Policy:

1. Activities that are routinely allowable upon disclosure pursuant to policy.
2. Activities that may be allowable following disclosure and, where necessary, the implementation of an approved management plan and monitoring procedures.

3. Activities that are presumptively not allowable, unless an approved management plan and monitoring procedures are in place.
4. Activities that are not allowable under any circumstances

C. Mechanisms for Disclosure and Identification of Potential Conflicts of Interest

Mechanisms through which potential Conflicts of Interest are disclosed and otherwise identified may include:

1. The Annual COI Disclosure process via the online Activities, Interests, and Relationships (AIR) system or other designated electronic system
2. Reported Conflicts of Interest that arise during the course of the year (i.e., the Conflict of Interest arises in between annual disclosure cycles)
3. Reviews of projects or protocols routed through any module of the UNCG SeRA system, to include RAMSeS and IRBIS.
4. External or other sources

It should be noted that the same situations involving potential Conflicts of Interest may be reported repeatedly across the different mechanisms for disclosure for any given person. That is, an individual may report a particular source of potential Conflicts of Interest via the annual disclosure process, which is also reported upon submission of a proposal for external funding via RAMSeS, which is also reported on an application to the Institutional Review Board for human subjects research via IRBIS. The electronic system serves as a repository for all disclosures that are received via the annual disclosure process and through the RAMSeS or IRBIS.

D. Conflict of Interest Officer

The role of the Conflict of Interest Officer(s) (as designated by the Director of the Office of Research Integrity) is to provide oversight for the implementation of the Conflict of Interest and Commitment Policy for Faculty and EHRA Non-Faculty employees. This includes monitoring disclosures reported through all sources listed above in Section B, ensuring that Conflict of Interest management plans are in place and on file when needed, and facilitating coordination among the various stakeholders who are charged with monitoring compliance issues in which conflict of interest plays a role (e.g., Office of Sponsored Programs and compliance with NHS and NSF reporting regulations; the Innovation Partnership Services Office and the Office of Research Integrity and oversight of the protection of human subjects in research).

The Conflict of Interest Officer provides initial review of newly disclosed sources of potential Conflicts of Interest. The COI Officer may determine, upon review, that no Conflict of Interest exists. In cases where the Officer deems a conflict may exist, multiple courses of action may take place, including:

1. Consultation with members of the Administrative Resource Team;
2. Referral to the Conflict of Interest Committee.

E. Administrative Resource Team

Ad Hoc Administrative Resource Teams are comprised of individuals whose roles and/or expertise may provide helpful information for the analysis of potential Conflicts of Interest. These teams include representatives from the following offices, but may be or narrowed or expanded as needed:

1. Office of Research Integrity
2. Office of Sponsored Programs
3. Innovation Partnership Services Office
4. Office of Contracts and Grants
5. Deans, Associate Deans or Directors of Research
6. Legal Counsel
7. Office of the Provost
8. Office of the Chancellor
9. Business Affairs
10. Department Chairs
11. Center Directors

F. Conflict of Interest Committee

Conflicts of Interest, and questions regarding objectivity that can arise, most commonly develop in the context of research, scholarship, and creative activities or in the development of teaching materials and methodologies. Peer review is the established mechanism for reviewing and ensuring the quality and integrity of intellectual endeavors in higher education. As such, the Conflict of Interest Committee (“Committee”) is a mostly faculty-based committee established to provide peer review of potential Conflicts of Interest and make recommendations for managing, reducing, and/or eliminating existing or potential Conflicts of Interest. The Committee acts in an advisory capacity to the Conflict of Interest Officer(s) in their determination of whether a conflict exists and any necessary actions needed to safeguard the integrity of the situation in question. The Committee may also be asked to provide feedback on process, procedures, and policy and provide guidance on educational outreach efforts and the general campus climate regarding Conflict of Interest.

1. Composition and Structure of the Committee
 - a. Appointments are made by the Provost (or their designee) for staggered two or three year terms.
 - b. Membership will include
 - i. One faculty member from each of the 7 academic units (7)
 - ii. Two non-faculty research scientist/center appointees
 - c. The COI Officer will act as chair of this committee and in an ex-officio capacity.
2. Meeting Schedule
 - a. The Committee will meet twice annually at a minimum.

- b. Additional meetings may be called as needed to address emerging situations involving potential conflicts of interest
3. Review procedures
 - a. The COI Officer will present the situation involving potential Conflict of Interest to the Committee members in written form prior to the meeting. At this time, the COI Officer will define the questions of interest for the Committee members to consider.
 - b. The COI Officer and/or Committee members may request that the employee/s involved in the situation be present at the meeting so that they can ask additional questions.
 - c. Recognizing that situations where there is potential conflict of interest may also evoke questions regarding other policies and procedures (e.g., use of university resources, personnel concerns), Committee members may also request that representatives of the administrative resource team (see D above) join the meeting so that all angles of the situation can be understood and addressed.
 - d. Written notes from the meeting will be documented and stored with the disclosure in the designated electronic system.

II. REVIEW GUIDELINES AND PROTOCOL

A. Guiding Principles

Detailed definitions, thresholds, and standards for the review and classification of situations involving potential Conflict of Interest are set forth in the University Conflicts of Interest and Commitment Policy and Federal guidelines (A summary of the PHS policy can be found: <http://grants.nih.gov/grants/policy/coi/>, and the applicable Federal Regulations (42 C.F.R. Part 50, Subpart F) can be found here: <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f>). The following principles, provide guiding principles for review, particularly for situations involving research.

1. Existing University policies, State law, and Federal laws and regulations dictate boundaries that employees must keep between their roles associated with the University and their private interests outside of the University.
2. The substance and impact of the project should be appropriate to the mission of the University. That is, the project should contribute to advances in scholarship and/or provide educational opportunities for students.
3. The conditions under which research and teaching take place should allow for the free exchange of ideas and materials, including the publication and dissemination of research results. Situations that would place restrictions on these activities should be carefully considered in light of University policies and should give reviewers pause.
4. Any proposed use of University resources should be appropriate per University

policy and State regulations. University resources should be defined in a broad sense, including equipment, office space, and staff time. This also includes resources unique to the university environment, such as students (e.g., in the testing of teaching materials), software (where license agreements often restrict use for instructional or academic purposes only), and the Institutional Review Board. University resources should not be used for personal or private gain, but are resources vested under our care for the public good.

5. The potential effect of any given financial interest on a situation or project should be viewed in terms of
 - a. The reasonable likelihood that the results of the project could directly affect the value of related products, services or intellectual property in which an entity outside the University has an interest; and
 - b. The reasonable likelihood that the results of the project significantly impact the value of the outside entity or its sales.

B. Small Business/STTR Grants

Of special note are Small Business Innovation Research (SBIR) grants and Small Business Technology Transfer (STTR) grants. Employees may not serve as the Principal Investigator of an SBIR/STTR grant for both the outside small business and the University, as this would render it impossible for the interests of the business and the University to be kept distinct. In general, employees who have a Financial Interest in an outside entity may not serve as the Principle Investigator of project involving that entity and the University. Additionally, there must be a very clear distinction between activities that are conducted at the University using University resources and activities performed at the small business site, and all work done using University resources must be consistent with University and State policy. Generally this means that the University's involvement in the project should be focused on long-range exploratory work without immediate commercial value.

C. Protocol for Review of Situations with Potential Conflict of Interest

The following is a delineated rubric for reviewing situations with potential conflict of interest. These steps apply to review whether by the COI Officer or COI Committee.

1. Review the details of the situation in light of relevant University, State, and Federal policies, guidelines, laws and regulations. Note that the National Science Foundation and Public Health Service have unique sets of regulations.
2. Take into account the nature and extent of the financial interest in question, including its impact on the employee, their Financial Interests, and the interests of the outside entity.
3. Particular attention should be paid when the situation involves research agreements that involve:
 - a. Product or invention testing, including testing of curricula or other teaching materials.
 - b. Research taking place off University premises.

- c. Research conducted in collaboration with employees from outside entities.
 - d. Research that includes the disclosure of proprietary information from an outside entity.
4. Particular attention should be paid when a University employee or a member of the employee's immediate faculty has the following relationships with an outside entity:
 - a. Ownership interest in the entity.
 - b. The possibility of receiving financial benefits from the entity (e.g., stock, bonuses).
 - c. A long term or ongoing consulting relationship with the entity.
5. Seek additional information from the employee and/or relevant members of the administration as needed.
6. As appropriate, ask the following questions to help determine whether a Conflict of Interest exists, and if so, its nature.
 - a. Is there reason to believe that the employee's financial relationship with the outside entity could jeopardize the employee's ability to conduct their work following all applicable policies and ethical standards? If research, could the employee's role in the design, conduct, or reporting of the project be subject to bias?
 - b. How will the University's interests and compliance obligations be protected in light of the employee's interest in the outside entity?
 - c. How will the project contribute to the University's teaching, research, and service mission?
 - d. Are there potential benefits to the public that outweigh any potential concerns related to academic freedom, professional relationships, or the public trust?

D. Management or Elimination of Conflict of Interest

If it is determined that a Conflict of Interest exists and must be managed or reduced, the COI Officer, in consultation with the COI Committee and/or Administrative Resource Team as appropriate, will determine the appropriate course of action.

1. There are many options available for management of Conflict of Interest, including
 - a. Notice to those involved in the project of the employee's Conflict of Interest
 - b. Appointment of additional, non-conflicted employees to monitor the project in terms of guarding against bias in research findings, providing additional accountability for financial matters, and/or protecting student interests.
 - c. Public disclosure of the Conflict of Interest
 - d. Acknowledgement of the Conflict of Interest in consent forms
 - e. Modification of the research or project design

- f. Removal of the employee from specific responsibilities
2. In some circumstances, elimination of the Conflict of Interest may be deemed necessary, including
 - a. Non-acceptance of the gift or grant
 - b. Withdrawal of the proposed project
 - c. Employee divestiture of the conflicted interest
3. The course of action decided upon should be documented in the form of a management plan. The management plan should be shared with and acknowledged by the employee's direct supervisor (e.g., department chair). When the project involves external funding and/or human subjects research, the management plan also must be signed by a representative of the Dean's Office (or equivalent) and the Vice Chancellor for Research and Engagement.
4. Management plans should be reviewed annually or any time that changes occur with the project that could impact the nature of the Conflict of Interest.
5. Approved management plans should be stored with the initial disclosure via the designated electronic system and shared with individuals responsible for their oversight.

E. Appeals

In the event that an employee feels that decisions regarding a Conflict of Interest are unreasonable, they may ask for a secondary review of the materials. Faculty appeals will be heard by the Provost or the Provosts' designee. Non-faculty appeals will be heard by the senior administrator best positioned to review the case, as designated by the Vice Chancellor for Research and Engagement.

F. Related Concerns

As detailed in the UNCG Policy on Conflict of Interest and Commitment, multiple policies, procedures, and regulations intersect with the review and management of potential conflicts of interest (e.g., personnel policies, regulations regarding the use of State resources, State purchasing guidelines). In situations where the predominant concerns regarding Conflict of Interest are administrative in nature (i.e., related to the administrative responsibilities of the employee), or involve personnel issues (e.g., resulting in conflicts between employees, jeopardizing the academic progress of students), the COI Officer may defer review of all or part of the situation to the appropriate senior administrator.

When a Conflict of Interest is related to human subjects research, the Institutional Review Board has final jurisdiction over decisions regarding project approval or disapproval and plans for managing the impact of Conflict of Interest on the project in question.

III. CONFIDENTIALITY AND RECORD KEEPING

Most elements of completed disclosure forms are confidential personnel records pursuant to N.C.G.S. § 126-22 et seq., governing the Privacy of State Personnel Records. The provisions of that statute governing access to and confidentiality of personnel records shall be strictly observed. The Conflict of Interest Committee will be notified and reminded regularly regarding the confidential nature of their work, and will maintain records in keeping with University records retention policy.

IV. CONTACTS FOR ADDITIONAL INFORMATION AND REPORTING

Alan Boyette, Senior Vice Provost
336-334-5494
Alan_Boyette@uncg.edu

Lisa Goble, Director of Research Integrity
336-256-1173
lagoble@uncg.edu