

**THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL**  
**POLICY ON INDIVIDUAL CONFLICTS OF INTEREST AND**  
**COMMITMENT**

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**I. INTRODUCTION AND PURPOSE**

Consistent with the University's research, teaching and public service mission, the University encourages faculty, staff and students to engage in appropriate outside relationships with private industry and the nonprofit sector. But members of the University community are expected to avoid conflicts of interest or commitment that have the potential to directly and significantly affect the University's interests, compromise objectivity in carrying out University responsibilities, or otherwise compromise performance of University responsibilities, unless such conflicts are reported, reviewed, and managed in accordance with this Policy. This Policy on Conflicts of Interest and Commitment (hereinafter, the "Policy") describes the University's approach and process for identifying, reviewing, and managing such relationships to help assure the integrity of University academic and administrative endeavors.

A member of the University community—faculty, staff, student or trainee -- may be deemed to have a conflict of interest when he or she or any of that person's family possesses a personal financial interest or external executive position related to an activity that involves his or her University responsibilities.

Through this policy we seek to minimize the most obvious and avoidable conflicts of interest that have potential for serious negative effects on performance of the University's missions. The requirement that an individual's potential conflicts of interest be reported and evaluated by others is not a commentary on the integrity of the individual. As members of a scientific and intellectual community we recognize that objectivity about one's own situation and credibility with external observers require an evaluation external to oneself. Moreover, the fact that an individual may be determined to have a conflict does not imply that the conflict is unethical or impermissible; it means simply that the relation of the conflict to the individual's University responsibilities must be carefully examined and in some cases managed, because conflicts - real or perceived - may impair performance of our missions of teaching, research, and public service, as well as jeopardize public trust and support.

## **II. COVERED INDIVIDUALS**

This Policy applies to all University employees, students and 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."

## **III. SPECIFIC TOPICS**

The University strives to ensure that all of its activities are conducted in accordance with high ethical standards and with federal and state law and regulation. Some activities by their nature require particular scrutiny for potential conflicts of interest.

### **A. Conflict of Commitment**

The term "conflict of commitment" relates to an individual's distribution of effort between University duties and external professional activities. All EPA Faculty and EPA non-Faculty employees of the University are expected to devote their primary professional loyalty, time and energy to their University responsibilities; accordingly, outside professional activities and outside financial interests must be arranged so as not to interfere with the primacy of University responsibilities.

In accord with the University of North Carolina Board of Governor's *Policy on External Professional Activities for Pay by Faculty and Non-Faculty EPA Employees*, all EPA Faculty and EPA non-Faculty employees of the University are required to receive approval in advance for external professional activities for pay (except for contract employees performing external professional activities for pay entirely outside the months of their University contract employment). University policy does not provide that a faculty member is entitled to engage in external professional activities for pay for any specific or set percentage of time. Rather, an employee's supervisor always has the

discretion to determine whether a proposed external activity is appropriate in scope and duration or constitutes excessive time away from University duties.

### **Required Reporting and Action:**

An EPA Faculty or non-Faculty employee is required to file a “Notice of Intent” with her/his department head at least ten (10) days before engaging in an external professional activity for pay. A University inventor seeking to engage in external professional activity with an entity that proposes to license, has licensed or has otherwise acquired rights to his or her invention must also file a copy of the “Notice of Intent” with the University’s Conflict of Interest Officer at least 10 days in advance of engaging in the external professional activity (See section “Intellectual Property Transactions” below). The department head is required to respond with approval or disapproval of the external professional activity for pay within 10 days of the filing of the “Notice of Intent.” See the *University Policy on External Professional Activities of Faculty and Other Professional Staff* for more detailed information.

### **B. Acceptance by Individuals of Gifts, Favors from External Entities**

Generally University employees may neither accept nor offer, either directly or indirectly, any personal gift or favor or loan to or from an organization, entity or person that is conducting or seeking to conduct business with the University, unless the gift is nominal. However, meals, texts, or customary honoraria may be provided to University faculty or EPA nonfaculty employees in connection with activities allowed under the *University Policy on External Professional Activities of Faculty and Other Professional Staff*. Although customary honoraria and reimbursement for actual costs generally are not considered to be gifts, if reimbursements or honoraria are significantly in excess of fair market value or customary amounts (e.g. expensive resort sojourns, coverage of family member expenses, etc.), they are defacto gifts.

A “nominal” gift occurs where the fair market value of all payments, gifts or favors from the same or related source within a single calendar year is less than forty dollars (\$40.00). Cash gifts of any size are not considered nominal.

University employees also may not accept any financial or other favors in exchange for privileged access by current or potential University vendors to University facilities or employees. Any personal compensation a University Project sponsor pays to or for the benefit of a covered individual outside of contracted project support to the University must be reported by the covered individual as applicable under the *University Policy on External Professional Activities of Faculty and Other Professional Staff* and this Policy.

A University employee may not receive compensation from an external source for performance of University work except through a University contract or grant.

### **C. Gifts to the University or an Affiliated Foundation for the Benefit of an Individual Employee or Student.**

For purposes of this Policy, 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 as required under this Policy for any other personal financial interest.

### **D. Use of University Resources, including Privileged Information**

Confidential or privileged information acquired by the University may not be used by a University employee for personal gain, nor may any employee permit unauthorized access to such confidential or privileged information. Insider trading is just one form of impermissible use of privileged information for personal gain. **University faculty and staff should be wary of consulting arrangements through which they may risk sharing confidential proprietary information acquired through sponsored University projects.**

University employees may not use for non-University purposes any University-funded or supported resources, including but not limited to University facilities, work product, results, materials, property records, or information developed with University funding or other University support except as otherwise allowed under University policy. This prohibition includes the use of the University's name in a manner that may imply that the University is associated in some way with the employee's external activity or interest. One context in which this might occur is an external professional activity for pay. Mere identification of the University as one's employer and of one's position at the University is permitted, provided that such identification is not used in a manner that implies sponsorship or endorsement by the University.

Use of University facilities and resources must be in accord with the University's *Policy on Use of University Facilities for Noncommercial and Commercial Purposes* and the University's *Personal Use Policy*.

### **E. Purchasing, Contracting, Other Business Transactions on behalf of the University**

A University employee generally may not participate in awarding, negotiating, reviewing or approving a financial transaction (including but not limited to purchases, contracts, and subcontracts ) involving the University and an entity in which the employee has a personal financial interest without prior review and approval as described immediately below. Where an employee is involved in the design, conduct or reporting of University research related to that employee's personal financial interest, that potential conflict of interest is governed by the sections below entitled "Intellectual Property Transactions" and "Research and Sponsored Projects." In addition, an employee may assist in the negotiation of license agreements for University intellectual property as allowed under the *Policy on Equity Acquisition*.

### **Required Reporting and Action:**

University employees routinely involved in the negotiation, approval or administration of University contracts with external entities must file an annual Conflicts of Interest Evaluation Form with the University's Conflict of Interest Officer. See the section below entitled "Exercise of University Administrative Responsibilities."

If a University faculty or staff member has not filed an annual Conflicts of Interest Evaluation Form disclosing a potential conflict of interest but is prospectively involved in awarding, negotiating, reviewing or approving a financial transaction involving the University and a private interest of that individual, the conflict of interest must be reported to the employee's supervisor. The supervisor shall reassign that transaction to another employee except with prior approval and such management as is deemed appropriate by the Conflict of Interest Officer. (See also the University's Business Manual, Material and Disbursement Services Policies No 17 and No. 22 and Appendix 12 <http://www.ais.unc.edu/busman/msd/msdpol17.html>.)

### **F. Intellectual Property Transactions**

The University's mission includes fostering the invention and development of new patentable and nonpatentable technologies. The University attempts to license many of these innovations to commercial entities so that University research results may reach the market for the public good. The University must be protected from both real and perceived inappropriate "pipelining" of University innovations to entities in which University inventors have personal financial interests, and University facilities and resources must not be used to the advantage of the licensee entity absent specific authorization consistent with University policy and procedures.

### **Required Reporting and Action:**

All University inventors are required to report their financial interests and those of their **family** in the course of the licensing process. Additionally, external consulting relationships between a University inventor and the holder of a University license for the inventor's technology are not permitted unless reviewed and approved in advance both as required under the *Policy on External Professional Activities of Faculty and Other Professional Staff* **and** by the University Conflict of Interest Officer.

All faculty, staff or student inventors of technologies licensed or otherwise made available through contract by the University to a third party must complete and submit a Project-Specific Conflict Evaluation Form before execution of the license or other agreement by the Office of Technology Development. Any University faculty, staff or student inventor who holds equity in, is an officer or director of, or provides consultative services to an entity that has licensed or otherwise acquired rights to University invention(s) will be deemed to have a conflict of interest under this Policy.

Updated forms must be submitted to the University's Conflict of Interest Officer promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Project-Specific Conflict Evaluation Form previously answered in the negative.

### **G. Exercise of University Administrative Responsibilities**

Individuals in administrative positions have substantial influence by virtue of their role in professional appointments, promotions, tenure decisions, allocations of space, determinations of salary, execution of business contracts, etc., and must take particular care to avoid relationships that have the potential to advantage the individual but adversely affect the University's interests or inject inappropriate considerations into administrative decisions. They must be vigilant in ensuring that their exercises of administrative decisions are not, and do not appear to be, colored by their personal financial interests. (Such relationships may also be prohibited under the *Policy on Institutional Conflicts of Interest*.)

#### **Required Reporting and Action:**

All University Deans, Vice Chancellors, Directors, Chairs, Department Administrators and Business Managers, and any other employee deemed by his or her supervisor to be routinely involved in review, award, or administration of University contracts must file an Annual Evaluation Form. In addition, because of the sensitivity of their positions, employees in the Office of University Counsel, Office of Research Compliance, Office of Material and Disbursement Services, Office of Technology Development, and Office of Sponsored Research also must file Annual Evaluation Forms pursuant to this section. Updated forms must be submitted promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Annual Evaluation Form previously answered in the negative.

Further information on reporting requirements is included in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

### **H. Exercise of University Review Panel Responsibilities**

There are also important conflict of interest responsibilities for individuals participating on panels providing administrative review and evaluation on behalf of the University – such as Institutional Review Boards (IRB), Institutional Animal Care and Use Committee (IACUC), Conflict of Interest review committees, purchase evaluation committees, etc.

## **Required Reporting and Action:**

If any individual member of a University review panel has a personal interest (including **family** member interests) in a matter subject to the panel's review, that individual must report the conflict of interest to the panel's chair. If the panel chair deems the conflict to be material to the matter under review, the panel member shall recuse himself or herself and shall not participate in the related review process. The recusal shall be documented in the panel's minutes.

## **I. Research and Sponsored Projects**

All University employees, students and trainees involved in the design, conduct or reporting of a University research or sponsored project must report any potential conflict of interest that they have related to the research or sponsored project. "Involved in the design, conduct and reporting" means to be part of the project in any capacity that allows for the possibility of affecting results of the project, including but not limited to serving as the principal investigator, co-investigator, research collaborator, research study coordinator, or research assistant. This requirement is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis).

Potential conflicts include any personal financial relationship (as defined by this Policy), regardless of level or type of compensation, and any uncompensated position, board membership, or consultancy with or for an external entity involved in the research or sponsored project in any way, including as a sponsor, subcontractor, subrecipient, or as an owner or licensee of any product, process or technology studied in the project. Whether a potential conflict of interest will be deemed an actual conflict of interest will depend on the nature of the potential conflict and on the nature of the University activities potentially affected by the potential conflict. Where an actual conflict of interest poses the risk that University activities may be inappropriately affected, the conflict must be eliminated. Subject to special provisions regarding particular types of University relationships (such as SBIR or STTR Agreements, *see below*), the following guidelines are generally applicable:

- (1) Where a Covered Individual proposes to be involved in the design, conduct or reporting of University research other than human subjects research, his or her conflict of interest may be allowed with University approval and appropriate management.
- (2) Where a Covered Individual proposes to be involved in the design, conduct or reporting of University human subjects research, he or she may not have a personal financial interest of any level or value reasonably judged to be materially related to the outcomes of such research, absent a showing by the Covered Individual of compelling circumstances justifying continuation of involvement in the project notwithstanding the personal financial interest.

(3) The training experience and academic progress of University students and trainees must not be subordinated to personal financial interest of Covered Individuals or commercial interests of research sponsors.

The University's Principal Investigator bears the responsibility to ensure that any potential conflict of interest that exists in relation to the research project he or she leads is reported as required in this Policy. University investigators are required to disclose in any publication or presentation of their research the existence and nature of all related personal financial interests and related external executive positions.

### **Federal Regulations**

Federal regulations require that when federal agencies fund University research through grant or contract, each University **investigator** must report through disclosure, and the University must examine, the **investigator's** related **financial interests**, which include those of the **investigator's family** (spouse or dependent children – see definition of **family**), that meet certain thresholds and report them to the federal agency involved. However, this Policy extends to all University research responsibilities, not just those that involve federal funding, and the University requires report and review of all related financial interests, not just of those that meet a given federal agency's threshold.

### **Subcontracts**

In addition, federal regulations require that if the University carries out any NIH -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 contractual assurance of their compliance with NIH's policy on Conflict of Interest. This contractual obligation 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.

### **SBIR/STTR**

Of special concern are federally sponsored SBIR or STTR research projects that involve association with small business entities. Due to the high potential for either the actual or the appearance of an irresolvable conflict of interest, a University employee may not conduct research or administrative activities in conjunction with a SBIR or STTR project on behalf of both the University and the grantee or sub grantee company without compelling evidence to support execution of both roles.

### **Required Reporting and Action:**

All University employees, students and trainees involved in the design, conduct or reporting of a University research or sponsored project who respond affirmatively to any Conflict of Interest question posed in the University's research review processes are required to complete and submit the Project-Specific Conflict Evaluation Form for each University project at initiation and at annual renewal. The form must be submitted to the University's Conflict of Interest Officer and processed as specified in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

Updated forms must be submitted to the University's Conflict of Interest Officer promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Project-Specific Evaluation Form previously answered in the negative.

When the need for a Project-Specific Evaluation Form is indicated through the review processes of the Office of Sponsored Research, any of the Institutional Review Boards, or any other University office, the research or other contract for which the form is indicated may not proceed until the potential conflict of interest has been reported, evaluated and approved or resolved. Violation of this provision by any University employee or student may lead to disciplinary action, up to and including dismissal from employment or enrollment.

Further guidance on disclosure requirements for Evaluation Forms is included in the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*.

### **IV. POLICY IMPLEMENTATION**

The Chancellor is responsible for overseeing the implementation of this Policy. Day-to-day responsibility for such implementation is delegated through the Research Compliance Director to the Conflict of Interest Officer.

In addition, the Chancellor will appoint a University Conflicts of Interest Advisory Committee, which will be authorized to make recommendations to the Chancellor for appropriate changes to this Policy, along with such other recommendations regarding the disclosure, evaluation, approval and management of conflicts of interest as the Committee deems appropriate. The Conflicts of Interest Advisory Committee will include the chairs of any college or school COI review committees, as well as such additional members as the Chancellor shall select upon advice of the Conflicts of Interest Officer in order to represent the interests and viewpoints of the members of the University community directly affected by and involved in implementation of this Policy.

Not less frequently than once each year, the Conflict of Interest Officer will compile a summary of the disclosures received and decisions made over the preceding academic year and submit a report to the University Conflicts of Interest Advisory Committee and the Chancellor.

## V. POLICY BREACHES

Possible sanctions for violation of this Policy, including furnishing false, misleading, or incomplete information, can range from administrative intervention to termination of employment or of enrollment, all in accordance with applicable University policies. The Chancellor, or the Chancellor's delegate, will review all alleged violations of this Policy, including the provisions of the *Standard Operating Procedures for Individual Conflicts of Interest and Commitment*. Violations may include but are not limited to: (a) failure to comply with the process (by failure to report timely a potential conflict as required, by failure or refusal to respond to requests for additional information, by providing incomplete or knowingly inaccurate information, or otherwise); (b) failure to remedy conflicts; and (c) failure to comply with a prescribed management agreement or monitoring plan.

## VI. DEFINITIONS OF SELECTED TERMS

**"Compelling Circumstances"** are those facts that convince the reviewer that a **covered individual** who has a **financial interest** should be permitted to conduct **human subjects research**, taking into account the following factors:

- (1) the nature of the research,
- (2) the magnitude of the **financial interest** and the degree to which it is related to the research,
- (3) the extent to which the **financial interest** could be directly and substantially affected by the research,
- (4) the degree of risk to the human subjects involved that is inherent in the research protocol,
- (5) the extent to which the investigator is uniquely qualified to perform a research study with important public benefit, and
- (6) the extent to which the interest is amenable to effective oversight and management.

**"Covered Individual"** refers to any University employee, student or trainee who is performing teaching, research, public service, administration and business operations of the University.

**"Executive Position"** refers to any position that includes responsibilities for a material segment of the operation, management or oversight of a **business**, including Board membership.

The **"Family"** of a **covered individual** includes his or her spouse and dependent children. For the purposes of this Policy, "spouse" 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.

**"Financial Interest"** means 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). **Financial interest** of a **covered individual** includes:

- (1) Salary, royalties (including royalties distributed to the **covered individual** or his or her **family** through the University), or other payments, including consulting fees or honoraria.
- (2) Equity interest held by the **covered individual** or his or her **family** in publicly-traded entities (does not apply to a mutual fund holding), or in entities that are not publicly traded.
- (3) Gifts that have been made to the University for the benefit of the research or other professional activities of a specific **covered individual** are deemed to be a personal **financial interest** of the **covered individual** for purposes of this University policy on conflict of interest.

**“Financial Interest”** does not include:

- (1) Salary or other remuneration from the University;
- (2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (3) Income from service on advisory committees or review panels or from editorial activities for public or nonprofit entities;
- (4) Interest in mutual funds where the **covered individual** has no control over the selection of holdings.

**“Human Subjects Research”** means any systematic investigation (1) that is designed to develop or contribute to generalizable knowledge and (2) that obtains data through intervention or interaction with living individuals and/or obtains identifiable private information about living individuals, including by means of the observation or recording of behavior. Intervention includes both physical procedures and manipulations of the subject or subject’s environment that are performed for study purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information that individuals can reasonably expect will not be made public. This definition also encompasses any experiment that involves a test article and one or more human subjects (i.e., a "clinical investigation" per FDA regulations).

**“Investigator”** means the principal investigator and any other person who is responsible for the design, conduct or reporting of research. Note that **financial interests** of the **investigator** include financial interests of the investigator’s **family**, as defined above.

**“University Project”** means any research, testing, evaluation, training, and/or instructional project conducted under the auspices of the University.