

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

January 8, 2008

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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 *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy).

### **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, which involve association with small business concerns. Because of the high potential for the appearance of an irresolvable conflict of interest, a University employee may not conduct research or



administrative activities in conjunction with an SBIR or STTR project on behalf of both the University and the grantee or sub grantee company.

**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 *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of 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 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 *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy).

**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, including *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy), along with such other recommendations regarding the disclosure, evaluation, approval and management of conflicts of interest as the Committee deems appropriate. Not less frequently than once each calendar year the Conflict of Interest Officer will submit a report to the University Conflicts of Interest Advisory Committee, summarizing disclosures received and decisions made over the preceding year. 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.

## 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 *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy). 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.

**"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.

## APPENDIX A

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

January 8, 2008

#### I. Introduction.

These Procedures, adopted by the Chancellor, are part of the Policy on Conflicts of Interest and Commitment (“the Policy”) and are intended to provide effective and transparent processes for the reporting, evaluation, approval or disapproval, and management of potential conflicts of interest within the University community. The Procedures do not apply to situations arising under the Policy on Institutional Conflicts of Interest or to situations governed by the Ethics in Government Act.

#### II. Reporting and Review of Project-Specific Potential Conflicts of Interest.

##### A. Potential Conflicts of Interest Reported in Conjunction with Proposed Research Grants and Contracts

In the internal processing form required in conjunction with every proposed grant or contract, the Office of Sponsored Research shall include questions supplied by the Conflicts of Interest Officer and designed to prompt reporting of potential conflicts of interest (COI). Where such potential conflicts are detected, the Covered Individual<sup>1</sup> shall submit a full Project-Specific COI Evaluation Form either in paper format or electronically, as specified by the COI Officer. While every effort shall be made to construct a practicable and efficient mechanism for detecting potential conflicts among all members of a research team involved, or anticipated to be involved, in the design, conduct or reporting of the research, it is the ultimate responsibility of the Principal Investigator to ensure that any potential COI among such persons is promptly and fully disclosed. These procedures shall also be required any time a grant or contract for research is renewed or extended.

Once submitted, a Project-Specific COI Evaluation Form will be promptly reviewed by the COI Officer, who will make a threshold determination of whether a potential COI exists. The COI Officer may contact the Covered Individual to gather additional or supplemental information necessary to evaluate the disclosure. If the COI Officer determines that no potential COI exists, the COI Officer will inform the Covered Individual in writing of that determination, with a copy to the appropriate official at the Office of Sponsored Research and to the Covered Individual’s department or unit head. If the COI Officer determines that a potential COI exists, the COI Officer will forward

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<sup>1</sup> Defined terms used in these Procedures shall have the meaning defined under the *Policy* unless otherwise noted.

the Project-Specific COI Evaluation Form, along with an analysis of the facts and issues presented, to a COI Review Committee with jurisdiction over the Covered Individual for review and advice on an appropriate resolution or, if necessary, management of the conflict. In schools, centers or departments that have no standing conflict of interest committee, this information will be submitted to, and such review and advice provided by the Dean or unit head.

Taking into account any advice given by a COI Review Committee or by other officers, the COI Officer will determine whether a COI exists and, if so, whether it can be managed or must be resolved in order for the research to proceed. The COI Officer may proceed to make a determination if no advice is provided by the applicable COI Review Committee or other officer within fourteen (14) days of transmission by the COI Officer of the COI Evaluation Form, provided that this deadline may be extended by the COI Officer for good cause and where doing so will not jeopardize the proposed research relationship.

The COI Officer shall make one of the following determinations and convey the decision in writing to the Covered Individual, with copy to the appropriate officer at the Office of Sponsored Research and to the Covered Individual's department or unit head:

- (i) No COI exists;
- (ii) A COI exists that is not subject to management by the University, and the COI must be resolved in order for the proposed research to be conducted under University auspices; or
- (iii) A COI exists that is subject to management by the University.

Where a COI is deemed to be subject to management, the COI Officer will promptly arrange a meeting with the Covered Individual to create a Management Agreement.

#### B. Potential COI Detected in Conjunction with Procedures for Review and Approval of Human Subjects Research by the Institutional Review Boards

The Office of Human Research Ethics shall include in the application form required in conjunction with every proposed research project under the jurisdiction of the Institutional Review Boards ("IRBs") questions supplied by the Conflicts of Interest Officer and designed to prompt reporting of potential conflicts of interest (COI). Where a potential conflict is detected, the Covered Individual shall submit a COI Evaluation Form to the COI Officer. These procedures shall also be required any time renewal of IRB approval is sought. Except as set out in this subsection (c), such Evaluation Forms shall be processed as provided in Section II.A., above.

No research described in an IRB application as to which a COI Evaluation Form has been submitted may proceed until the potential COI has been evaluated, approved or disapproved, and resolved or managed. The COI Officer shall inform the Covered

Individual in writing of any decision involving the COI Evaluation Form, with copy to the IRB with jurisdiction and to the Covered Individual's department or unit head. The IRB retains final jurisdiction over human subjects research and may decline to approve an application on grounds of COI notwithstanding a decision by the COI Officer that there is no COI or that a COI is present but capable of being managed.

#### C. Potential COI Disclosed by Inventors of Technologies Licensed by the University

Before executing a license agreement or other agreement making University technology available to another entity, the Office of Technology Development shall cause every inventor of the affected technology to complete a form containing questions supplied by the Conflicts of Interest Officer and designed to prompt reporting of potential conflicts of interest (COI). Where such potential conflicts are detected, the Covered Individual shall submit a full Project-Specific COI Evaluation Form to the COI Officer.

Because the Policy provides that any such Covered Individual 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 COI, the COI Officer may review all such disclosures without advice from the Conflict of Interest Review Committee or other officer with jurisdiction. In instances where the Covered Individual discloses a COI, the COI Officer will meet promptly with the Covered Individual to create a Management Agreement.

When, subsequent to execution of a license or other applicable agreement, the Office of Technology Development agrees to add technologies to those already covered under the agreement, any additional inventors shall be required to complete the required form to screen for potential conflicts. Where potential conflicts are detected the Covered Individual shall submit a full COI Evaluation Form to the COI Officer, who shall process it as specified above.

### III. Reporting and Review of Annual COI Evaluation Forms.

The COI Officer shall create a schedule of required submission dates for University employees specifically required by the Policy to submit COI Annual Evaluation Forms. Such Forms shall be designed by the COI Officer and where practicable shall be filed electronically. Any employee who fails to file a required form on or before the date specified by the Conflict of Interest Officer other than for good cause (as determined by the COI Officer) shall be deemed to be in violation of the Policy and subject to disciplinary action up to and including dismissal.

The Conflict of Interest Officer will review all Annual Evaluation Forms and determine whether or not the information disclosed in each represents a potential COI. Upon making the determination that there is a potential COI, the COI Officer will forward the applicable Evaluation Form with a preliminary analysis and recommendation

for resolution to the Vice Chancellor or other officer with analogous administrative authority (“the reviewing officer”) supervising the affected Covered Individual.

The reviewing officer shall issue a decision regarding the disclosure within fourteen days of receipt of the Annual Evaluation Form, provided that that deadline may be extended by the COI Officer for good cause. Where the reviewing officer agrees with the COI Officer’s analysis, the Covered Individual will be required to recuse himself or herself from any University activities affected by his or her COI. In situations where recusal of the Covered Individual cannot be effected consistent with his or her University duties, the Covered Individual will be required to resolve the COI by divestment of the personal financial interest causing the COI.

Where the reviewing officer disagrees with the COI Officer’s conclusion that a COI exists, he or she shall set out the basis for that decision in a memorandum to the Chancellor, with a copy to the COI Officer and the Covered Individual. The Chancellor may accept or reject the reviewing officer’s decision and order such further measures to resolve or manage the COI as the Chancellor deems appropriate.

#### IV. Management of Research-related COI

##### A. Management Principles

The COI Officer is responsible for designing appropriate management mechanisms for approved conflict of interest activities (hereinafter referred to as an “approved COI”). The COI Officer may seek advice from individuals outside as well as within the University in proposing such mechanisms.

Questions to consider in constructing an optimal management plan may include:

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the University?
- Will the research work plan receive independent peer review prior to its initiation?
- Are there mechanisms in place to prevent the introduction of bias into research projects?
- Will the project be supervised or monitored by someone with authority over the investigators and no conflicting interests?
- Are there independent means to verify research results?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility of such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed literature?
- Will the sponsorship and relevant personal financial and executive interests be disclosed in publications and public presentations of the research results?

- In human subjects research, what are the protections for human subjects in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting?

The goal in addressing these questions should be to determine the appropriate mode of dealing with any real or apparent conflicts. Possible measures to be taken in managing a COI include, but are not limited to, any of the following:

- Public disclosure of financial interests;
- Reformulation of the work plan;
- Close monitoring of the project; independent review committee;
- Substituting supervisors and/or any other research personnel;
- Divestiture of financial interests;
- Termination or reduction of involvement in the relevant projects;
- Termination of inappropriate student involvement in projects;
- Severance of relationships that pose actual or potential conflicts;
- Separation of the Covered Individual from involvement in human subjects research in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting.

## B. Management Agreements

The preferred mechanism for managing research related COI will be the management agreement. The management agreement is an agreement entered into by the COI Officer on behalf of the Chancellor and by the Covered Individual, setting out the terms and conditions under which the Covered Individual will be allowed to continue University activities concurrently with a COI. The management agreement should address all relevant aspects of the conflict of interest, including but not limited to any reformulation or termination of the role of the conflicted covered individual in the University activity, any divestitures, any required disclosures and recusals, etc.

The following will be required elements of every management agreement:

(1) Acknowledgement by the Covered Individual that compliance with the terms of the management agreement, the Policy and these Guidelines is a condition of his or her employment or enrollment at the University, and that violation of those terms, the Policy or the Guidelines may lead to disciplinary action, up to and including dismissal or expulsion.

(2) Provision for the COI Officer to meet regularly with the affected Covered Individual and his or her department or unit head to review the circumstances of the activities addressed by the management agreement and address questions or concerns.

(3) Provision for the COI Officer to meet annually with the Covered Individual together with the covered individual's lab staff (students, trainees (e.g., post-doctoral fellows, residents, or in some cases junior faculty) and technical staff) to review



the facts of the COI under management, to inform the lab staff of any management agreement provisions of which they should be aware, and to provide information on how the lab staff can seek advice and assistance on any concerns they may have related to the COI.

(4) Agreement by the Covered Individual that the COI will be disclosed in all publications or presentations of research results related to the COI. (The Agreement may, but need not, spell out specific language to be used in such disclosures.)

(5) Agreement by the Covered Individual that he or she will not disclose confidential research information or intellectual property to the entity with which the Covered Individual has a financial relationship giving rise to the COI (“the related entity”) except through the Office of Technology Development, the Office of Research Services or some other appropriate University office or official.

(6) Agreement by the Covered Individual that he or she will not make University space, facilities or resources available to the related entity except as allowed under the University Leased Space Policy.

(7) Agreement by the Covered Individual that he or she will submit to the COI Officer for review any consulting agreement, employment agreement or agreement for services between the Covered Individual and the related entity in advance of execution of such agreement.

(8) Agreement by the Covered Individual that he or she will promptly submit an updated COI Evaluation Form should the circumstances of the Covered Individual’s relationship with the related entity change in any material respect.

### C. Monitoring

The COI Officer may monitor an approved COI, appoint an individual to do so, or appoint a monitoring committee of disinterested faculty members or of individuals from outside the University. Any person appointed to monitor a conflict who is not a University employee must sign a statement acknowledging his or her obligation to maintain the confidentiality of employee personnel records and proprietary information and data, including the Conflicts Evaluation Form. Monitors should be disinterested, free of financial or supervisory ties to the Covered Individual whose conflict is being monitored, and should have or have access to expertise sufficient to allow meaningful review of the conflict being monitored. The COI Officer, together with any monitoring committee, will design a monitoring plan that will address the principles set out in Section IV.A. above.

### D. Auditing

The COI Officer shall conduct random audits of approved COI in order to assure (1) that the individual COI is being managed appropriately and (2) that any systemic

weaknesses in COI review, approval and management at the University are identified and resolved. All Covered Individuals shall cooperate with such audits, including requests for documentation, and failure to do so shall be deemed a violation of the Policy.

#### V. Investigation and Resolution of Policy Violations

Any time the COI Officer becomes aware of a potential violation of the Policy or of any other situation that could indicate that University research, education and training may have been affected inappropriately by a conflict of interest, the COI Officer shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

A. On receipt of such a report, the COI Officer shall notify the General Counsel and the Director of Research Compliance. In consultation with those persons, the Conflict of Interest Officer may:

- (1) Investigate the matter and make a written memorandum of his or her conclusions;
- (2) Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or
- (3) Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns and a personal interview with the Covered Individual, who should be informed with specificity of the allegations or concerns that have arisen. While the Covered Individual has a right to know the identity of a person making such allegations, he or she should be informed that University policy prohibits retaliation against a person making such allegations in good faith.

B. Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that University research, education, training, business administration or other performance may have been affected inappropriately by a conflict of interest, the COI Officer should take any steps necessary to correct the situation, including and up to disallowance of the original conflict of interest being managed. In addition, where appropriate the Conflict of Interest Officer must consider recommending to the relevant officials the imposition of disciplinary or other action under other appropriate University policies, including the Policies and Procedures on Ethics in Research and disciplinary policies for faculty, staff or students. The COI Officer, in consultation

with the Vice Chancellor for Research and Economic Development, shall have the authority to direct that the research activities of the Covered Individual affected by the COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending amelioration of the Policy violation.

- C. Upon determination that no violation of the Policy has occurred, or otherwise at the conclusion of any investigation conducted under this Policy, all materials generated in the course of such investigation should be placed with the Covered Individual's personnel file or, if a student, with the Office of the Vice Chancellor for Student Affairs, marked as "confidential" and stored in a secure manner, in order to ensure the confidentiality of these records.

## VI. Records Confidentiality and Retention

### A. Confidentiality

The COI Evaluation Form contains information that may have a direct bearing on a Covered Individual's employment and is considered to be confidential personnel information that should be maintained in a secure and confidential file. The information reported in the COI Evaluation Form is available only to individuals duly charged with the responsibility for review, and may be released only in accordance with and as required by North Carolina law or lawful court order.

### B. Records Retention

All records relating to the reporting of potential Conflicts of Interest and Commitment, and to the actions taken with respect to those reports, shall be maintained for three years following the expiration of their relevance, or as required by applicable government regulations, whichever is greater.

