03.230  CONFLICT OF INTEREST OR COMMITMENT

Authority: Chancellor

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Source of Authority: UNC Policy Manual, Section 300.2.2

Related Links: HHS Federal Register 42 CFR Part 50 Subpart F and 45 CFR Part 94; Conflict of Interest Annual Reports; UNC Policy Manual 300.2.2.1[R]; UNC Policy Manual 300.2.2[R]

Responsible Office: Office of Research Services

I. Policy and Scope

This policy sets forth procedures for implementation of the UNC Board of Governors policy and guidelines concerning conflicts of interest and commitment affecting University employment. Procedures for implementation of the policy and compliance with required reporting mechanisms are contained within this document. In addition, the realms of conflict of commitment and conflict of interest are explained together with how each is to be monitored. All EPA faculty and professional employees are covered by this policy.

*The Code of the University of North Carolina* affirms that the basic mission of the faculty is "the transmission and advancement of knowledge and understanding." Faculty employment entails the core responsibilities of teaching, scholarly research and publication, and other professional service to the institution and to society. Realization of those objectives is facilitated and encouraged by certain distinctive characteristics of work-day and work-week employment models in most business and industrial settings.

Faculty members pursue their specialized professional interests in other contexts, collateral to their immediate University employment. They hold memberships in and attend meetings of professional associations and learned societies; they serve on review or advisory panels; they present lectures, papers, concerts and exhibits; they participate in seminars and conferences; they review and edit scholarly publications; and they participate in accreditation reviews. Faculty and non-faculty EPA employees (“Covered Employees”) have opportunities to use their specialized competencies in secondary professional employment, as paid consultants to public and private agencies, and thereby contribute to the transfer and application of knowledge.
As relationships between Covered Employees and private industry, federal and state governments, and nonprofit agencies have grown in number and scope, there has been a corresponding increase in concern about conflicts of interest and commitment. While these Covered Employees are encouraged to engage in appropriate relationships with public and private agencies outside of the University, there is a need for commonly understood principles and corresponding procedures that will identify, address and manage potential conflicts that would detract from or interfere with a Covered Employee’s dedication of unbiased primary professional loyalty, time, and energy to University teaching, research, and service.

All members of the University community are expected to avoid conflicts of interest and conflicts of commitment that have the potential to directly and significantly affect the University’s interests or compromise their objectivity in carrying out their University Employment Responsibilities, including research, service and teaching activities and administrative duties, or otherwise compromise performance of University responsibilities, unless such conflicts are disclosed, reviewed and appropriately managed in accordance with the provisions of this Policy.

It is the policy of the University of North Carolina Wilmington that activities undertaken by its faculty, staff and students in furtherance of the mission of the University shall be conducted in an ethical and transparent manner consistent with federal and state law and university policy.

In addition, there are specific training and reporting requirements for individuals that apply for, or receive, Public Health Service (PHS) funding by means of a grant or cooperative agreement. The U.S. Public Health Service (PHS) issued a final rule August 25, 2011 changing the requirements for the disclosure and reporting of financial interests of faculty researchers and institutions that apply for or receive funding from the Public Health Service. UNC institutions and PHS-funded researchers must be in compliance with the final rule by August 24, 2012. The primary interest of PHS is to achieve greater transparency, greater assurance that research results are not biased and greater accountability from institutions and investigators.

II. Introduction

Interactions between universities and external organizations have increased significantly in recent years and now frequently involve relationships among one or more universities and many external partners. These often complex relationships require that guidelines, such as this Policy on Conflict of Interest, be used to assure the importance of academic integrity in research.

In order to fulfill its teaching/research/outreach mission, UNCW encourages its faculty and other EPA employees to participate in meaningful and appropriate relationships with business and governmental partners. These partnerships are therefore established for mutually beneficial reasons and many times produce knowledge that will help to meet the needs of the community UNCW reflects and serves.
In order to preserve the employee's freedom to participate in these activities while avoiding real as well as perceived conflicts of interest, this uniform policy, consistent with current HHS, PHS, NIH and NSF guidelines, was developed for UNCW. All faculty and EPA non-faculty employees are required by this Policy to avoid conflicts of interest and conflicts of commitment in their relationships with external organizations.

This Policy covers full-time and part-time faculty and EPA non-faculty employees insofar as their University responsibilities are concerned with additional specific requirements for individuals that apply for or receive, Public Health Service (PHS) funding by means of a grant or cooperative agreement. It also covers faculty and EPA non-faculty employees who are on leave if the leave is funded at least partially from University sources.

The Policy provides an annual and ongoing disclosure and approval process for certain external relationships, but, recognizing the difficulty of anticipating all situations that may arise, leaves it to the discretion of the supervisor of the faculty member or EPA non-faculty employee to interpret and implement the Policy and to evaluate the proposed activity. The supervisor has the initial responsibility to review proposed activities for possible conflict of interest or commitment, according to the guidelines of this Policy.

The rigorous application of this Policy will be particularly important in the case of persons exercising significant University authority. Individuals in administrative positions have substantial influence over others by virtue of their role in professional appointments, promotions, tenure decisions, allocations of space, determinations of salary, and the like.

While this Policy is applicable to all faculty and EPA non-faculty, those with administrative responsibilities must take particular care to avoid relationships that have the potential to advantage the individual but affect adversely the University's interests. Among the relationships that may adversely affect the University's interests are relationships that would lead inappropriately to the individual's personal financial gain, relationships that might adversely affect the professional academic advancement of colleagues, or relationships that might otherwise inject inappropriate considerations into administrative decisions.

Of particular concern is the impact on students and other trainees of activities that could potentially create conflicts of interest or commitment. Because of this concern, it is essential that all faculty and EPA non-faculty employees demonstrate at all times their commitment to the highest intellectual and ethical standards in all aspects of research, teaching, and outreach, particularly where opportunities for conflict may exist. As a corollary, the training experiences of students are expected to incorporate the value of objectivity and the importance of public trust.

Because of the necessity to avoid conflicts of interest and commitment and the appearance thereof, the Policy requires each faculty member and EPA non-faculty
employee to disclose annually and as needed certain financial and other information. Individual circumstances may require additional or more frequent disclosure, particularly if there is any significant change in personal financial or fiduciary status. The information provided must be accurate and may have a direct bearing on the individual's employment status with the University. Possible sanctions for violation of this Policy, including refusal to file the disclosure form or furnishing false, misleading, or incomplete information on the disclosure form, can range from administrative intervention to termination of employment, all in accordance with applicable University policies. Examples of how conflicts of interest might be managed by the University are listed below. If a violation of this policy involves an externally-funded program, the Institutional Official will notify the funding agency of the corrective measures taken or planned.

III. Definitions

A. Conflict of Interest relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a Covered Employee’s objectivity in fulfilling their University duties or responsibilities, including research, service and teaching activities and administrative duties. The bias that such conflicts may impart can affect many University responsibilities, including decisions about personnel, the purchase of equipment and other supplies, the selection of instructional materials for classroom use, the collection, analysis and interpretation of data, the sharing of research results, the choice of research protocols, the use of statistical methods, and the mentoring and judgment of student work. A Covered Employee may have a conflict of interest when he or she, or any member of that person's immediate family has a personal financial interest in an activity that may affect decision making with respect to his or her Employment Responsibilities. For the purposes of this Policy, a Covered Person’s immediate family includes that person’s spouse and dependent children. While a Conflict of Interest may result from nonfinancial interests or considerations, the overwhelming majority of Conflicts of Interest result from a Financial Interest of a Covered Employee who is in a position to make a supervisory, academic, or administrative decision which may be compromised because of potential financial gain from a Financial Interest.

B. Financial Interest is defined as:

1. Payment for services to the Covered Employee not otherwise defined as institutional salary (e.g. consulting fees, honoraria, paid authorship);

2. Equity or other ownership interest in a publicly or non-publicly traded entities (e.g. stock, stock options, or other ownership interest); or

3. Intellectual property rights and interests upon receipt of income related to such rights and interest, held by the Covered Employee or members of his/her immediate family.
Income from investment vehicles, such as mutual funds or retirement accounts, in which the Covered Employee or member of his/her immediate family do not directly control the investment decisions and intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are excluded from the definition of Financial Interest. Covered Employees are required to disclose Financial Interests in a timely and accurate manner consistent with the implementing policies of the Constituent Institutions.

C. **Conflict of Commitment** relates to an individual's distribution of time and effort between obligations to University employment and participation in other activities outside of University employment. The latter may include such generally encouraged extensions of professional expertise as professional consulting (i.e. External Professional Activities for Pay). Such activities promote professional development and enrich the individual's contributions to the institution, to the profession, and to society. However, a conflict of commitment occurs when the pursuit of such outside activities involves an inordinate investment of time or is conducted at a time that interferes with the employee’s fulfillment of University Employment Responsibilities.

D. **External Professional Activities for Pay** is defined as any activity that 1) is not included within one's University employment responsibilities 2) is performed for any entity, public or private, other than the University employer; 3) is undertaken for compensation; and 4) is based upon the professional knowledge, experience and abilities of the employee. Activities for pay not involving such professional knowledge, experience and abilities are not subject to the advance disclosure and approval requirements of Section III of this policy, although they are subject to the basic requirement that outside activities of any type must not result in the neglect of primary University duties, creation of Conflicts of Interest, involve inappropriate uses of the University name or resources, or include claims of University responsibility for the activity. External activities for pay of employees covered by the State Personnel Act are addressed in the State Personnel Act, Section 3 Employment and Records, Secondary Employment.

E. **University Employment Responsibilities** include "Primary Duties" and "Secondary Duties." Primary Duties consist of assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties. Secondary Duties may include professional affiliations and activities traditionally undertaken by Covered Employees outside of the immediate University employment context. Secondary Duties may or may not entail the receipt of honoraria, remuneration (see additional regulations, *UNC Policy Manual, 300.2.2.2 [R]*) or the reimbursement of expenses, include membership in and service to professional associations and learned societies; membership on professional review or advisory panels; presentation of lectures, papers, concerts or exhibits; participation in seminars and conferences; reviewing or editing scholarly publications and books without receipt of compensation; and service to accreditation bodies. These activities, which demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and
effective performance of the individual's Primary University Duties or University policies.

F. **Covered Employee** is defined as any faculty or EPA non-faculty person employed by the University of North Carolina or a Constituent Institution, an affiliated entity, or other agency or unit of the University of North Carolina. The implementing policies of Constituent Institutions may further define Covered Employee to include additional classifications of personnel and students, which would further be considered Covered Individuals.

G. **Constituent Institution**, for the purposes of this policy, includes affiliated entities of the University of North Carolina, General Administration, and units associated with General Administration. Affiliated entities and other units of General Administration may implement Conflict of Interest policies consistent with this policy or adopt the policy of one of the constituent institutions.

H. **Department** means an academic department, a professional school without formally established departments, or any other administrative unit designated by the chancellor of an institution or by General Administration, for the purposes of implementing this policy. “Department Head” refers to the person with supervisory responsibility for the Covered Employee, whether in an academic or non-academic department.

I. **Inappropriate use or exploitation of University Resources** means using any services, facilities, equipment, supplies or personnel which members of the general public may not freely use for other than the conduct of Institutional Responsibilities. A person engaged in external professional activities for pay may not use University Resources in the course and conduct of externally compensated activities, except as allowed by the constituent institution’s implementing policies and other applicable University policies. Under no circumstances may any employee use the services of another employee during University employment time to advance the externally compensated employee’s professional activities for pay.

IV. **Conflicts of Commitment**

Questions about conflict of commitment are more easily resolved than questions about Conflicts of Interest. Although full-time faculty and other non-faculty EPA employment is not amenable to precise, time-clock analysis and monitoring, administrators at the department and school levels regularly evaluate the work of employees within their units. The formal occasions for determining whether an individual is devoting sufficient time and energy to University employment include regular reviews of performance in connection with annual salary decisions and scheduled reviews incident to promotion, reappointment or tenure decisions. In addition, complaints from students, colleagues, or administrators about possible failures to meet assigned responsibilities may arise and require investigation. The issue, in each case, is whether the employee is meeting the requirements of the job. If presented with evidence that he or she is not meeting full-time responsibilities to the University, *The Code* prescribes that "neglect of duty" is a ground
for disciplinary action, including the possibility of discharge. The following describe instances of activities that require specific monitoring to demonstrate the absence of conflict.

A. External Professional Activities for Pay

The University of North Carolina and its constituent institutions seek to appoint and to retain, as employees, individuals of exceptional competence in their respective fields of professional endeavor. Because of their specialized knowledge and experience, these individuals have opportunities to apply their professional expertise to activities outside of their University employment, including secondary employment consisting of paid consultation with or other service to various public and private entities. These practical compensated applications of their professional qualifications enhance capabilities in teaching, research, and administration. Thus, participation of employees in external professional activities for pay, typically in the form of consulting, is an important characteristic of academic employment that often leads to significant societal benefits, including economic development through technology transfer. However, such external professional activities for pay are to be undertaken only if they do not:

1. Create a Conflict of Commitment by interfering with the obligation of the individual to carry out all primary University Employment Responsibilities in a timely and effective manner;

2. Create a Conflict of Interest vis-a-vis the individual's status as Covered Employee of the University;

3. Involve any inappropriate use or exploitation of University resources; or

4. Make any use of the name of the University of North Carolina or any of its constituent institutions for any purpose other than professional identification;

5. Claim, explicitly or implicitly, any University or institutional responsibility for the conduct or outcome of the External Professional Activities for Pay.

The UNC Policy Manual, 300.2.2.1 [R], contains provisions established to monitor possible Conflicts of Commitment. A faculty or non-faculty EPA employee who wishes to engage in External Professional Activity for Pay must adhere to these regulations to provide satisfactory assurances that such activity will not interfere with University Employment Responsibilities. These regulations may not apply to faculty and non-faculty EPA employees serving on academic year (9-month) contracts, if the External Professional Activity for Pay is wholly performed and completed outside of the contract service period and the activity does not conflict with the policies of the Constituent Institution or Board of Governors and is not conducted concurrently with a contract service period for teaching, research, or other services to the institution during a summer session.
In those instances when State-reimbursed travel, work time, or resources are used or when the activity can be construed as related to the Covered Employee’s University Employment Responsibilities on behalf of the State, the employee shall not receive any financial consideration, including an honorarium. In these instances the employee may request that the honorarium be paid to the University. The honorarium may be retained by the employee only for activities performed outside of normal working hours, as defined by the institution, or while the employee is on earned paid or annual leave, and all expenses are the responsibility of the employee or a third party that is not a State entity. Third party support may need to be disclosed under the implementing policies and procedures for Constituent Institutions. In addition, senior academic and administrative officers may also be subject to special regulations regarding honoraria which require leave to be taken when External Professional Activities for Pay will take place during the regular work week. Please refer to the UNC Policy Manual, 300.2.2.2[R].

Instead of using earned paid or annual leave as set out above employees who are exempt from the Fair Labor Standards Act and who are out of work due to an External Professional Activity for Pay, or who wish to retain an honorarium, may be able to use periodic uncompensated leave rather than annual leave, provided the Constituent Institution implementing policies allow the use of uncompensated leave, and the appropriate Department Head approves.

External Professional Activities for Pay performed for another UNC Constituent Institution or agency of the State of North Carolina also must comply with applicable State policies governing dual employment and compensation, unless an exception to those State policies is expressly authorized by the chancellor or the President. The Board of Governors has also established rules for monitoring and regulating the involvement of University employees in political candidacy and office-holding that could interfere with full-time commitment to University duties. Please refer to UNC Policy Manual, 300.5.1 et seq. for specific policy details.

V. Conflicts of Interest

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty about situations that generate conflicts of interest related to institutional responsibilities, provides mechanisms for individuals and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every individual has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an individual should discuss the situation with the Institutional Official.

Conflicts of interest are more difficult to define, detect, and resolve than conflicts of commitment. An EPA employee’s professional activities and financial interests must be arranged to avoid circumstances that do or may prevent or limit objectivity in the
performance of University responsibilities or that otherwise do or may affect adversely any University interests.

I. Categories of Potential Financial Conflicts of Interest

Activities that may involve financial conflicts of interest may be categorized under four general headings: first, those that are allowable and are disclosed; second, those that are allowable with administrative approval and are disclosed; third, those that generally are not allowable and require an approved conflict of interest management plan; and fourth, those that are not allowable under any circumstances. The following examples are merely illustrative and do not purport to include all possible situations within the four categories:

A. Activities that are allowable and are disclosed

The examples cited below involve activities external to University employment, and thus may present the appearance of a financial conflict of interest, but have little or no potential for affecting the objectivity of the Covered Employee’s performance of Institutional Employment Responsibilities; at most, some such situations could prompt questions about conflicts of commitment.

1. A Covered Employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the UNC Patent and Copyright Policies.

2. A Covered Employee receiving compensation in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works and participation in accreditation reviews.

B. Activities requiring disclosure for further administrative review and analysis

The examples cited below suggest a possibility of conflicting interests that can impair objectivity, but disclosure and resulting analysis of relationships may render the activity permissible and may result in the establishment of an approved management plan.

1. A Covered Employee requiring students to purchase the textbook or related instructional materials of the employee or members of his or her immediate family, which produces compensation for the employee or family member.

2. A Covered Employee receiving compensation or gratuities from any individual or entity doing business with the University. Note that no university employee may seek or receive any gift, reward, or promise of reward for recommending, influencing, or attempting to influence the award of a contract by his or her employer (See G.S. 14-234 and G.S 138A).
3. A Covered Employee serving on the board of directors or scientific advisory board of an enterprise that provides financial support for University research and the employee or a member of his or her immediate family may receive such financial support.

4. A covered employee or a member of his /her immediate family having an equity or ownership interest in a publicly or non-publicly-traded entity or enterprise.

5. Covered Employee accepting support for University research under conditions that require research results to be held confidential, unpublished, or inordinately delayed in publication. Research conducted by faculty or students under any form of sponsorship must maintain the University's open teaching and research philosophy and must adhere to a policy that prohibits secrecy in research. Such conditions on publication must be in compliance with *UNC Policy Manual, 500.1* and *500.2*, and with campus Intellectual Property policies.

C. Activities or relationships that are generally not allowable or permitted unless an approved Conflict of Interest Management Plan is in place

The examples cited below involve situations that are not generally permissible, because they involve potential financial conflicts of interest or they present obvious opportunities or inducements to favor personal interests over institutional interests. Before proceeding with such an endeavor, the Covered Employee would have to demonstrate that in fact his or her objectivity would not be affected and University interests otherwise would not be damaged and an approved Conflict of Interest Management Plan is in place.

1. A Covered Employee participating in University research involving a technology owned by or contractually obligated to (by license or an option to license, or otherwise) an enterprise or entity in which the individual or a member of his or her immediate family has a consulting relationship, has an equity or ownership interest, or holds an executive position.

2. A Covered Employee participating in University research which is funded by a grant or contract from an enterprise or entity in which the individual or a member of his or her immediate family has an equity or ownership interest.

3. A Covered Employee assigning students, post-doctoral fellows or other trainees to University research projects sponsored by an enterprise or entity in which the individual or a member of his or her immediate family has an equity or ownership interest.
D. Activities that are not allowable under any circumstances

1. A Covered Employee making referrals of University business to an external enterprise in which the individual or a member of his or her immediate family has a financial interest.

2. A Covered Employee associating his or her own name with the University in such a way as to profit financially by trading on the reputation or goodwill of the University.

3. A Covered Employee making unauthorized use of privileged information acquired in connection with one's University responsibilities.

4. A Covered Employee signing agreements that assign Institution patent and other intellectual property rights to third parties without prior Institutional approval.

5. Any activity otherwise prohibited by law or university policy

VI. Public Health Service/US Department of Health and Human Services

The Public Health Service (PHS) and the U.S. Department of Health and Human Services issued revised regulations on the “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors” (commonly known as the Financial Conflict of Interest (FCOI) regulations) on August 25, 2011. These regulations establish new standards and clarify previously issued standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations were written to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigator’s financial conflicts of interest, and strengthen PHS’s compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and research contracts will be free from bias resulting from Investigator financial conflicts of interest.

Major changes to the 1995 PHS regulations are outlined below and are required for individual that apply for or receive Public Health Service (PHS) funding by means of a grant or cooperative agreement:

1) Key Definitions

a) Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.
b) *Investigator* means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk increases that an unidentified FCOI may comprise the research.

c) *Institutional responsibilities* are defined by the 2011 revised regulation as an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. The Institution can include other professional responsibilities within the definition, as appropriate.

d) A *Financial Conflict of Interest* exists when the Institution, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

e) *Significant Financial Interest* is defined as follows:

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse
or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available)

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

2) Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by September 15.
b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

3) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator’s research.

4) Clinical Trials

a) Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial

5) Reporting to PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

6) Investigator Non-Compliance
a) Disciplinary Action

In the event of an Investigator’s failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

A Institutional Official’s decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, a COI Committee, and, where applicable, the IRB and/or IACUC, and will notify the individual of the right to appeal the decision.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator’s failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a COI committee appointed by the Institutional Official will complete a retrospective review of the Investigator’s activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

7) Training

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the
Investigator has not complied with this policy or with a management plan related to their activities.

For the purposes of this policy sufficient training is demonstrated by completion of the UNCW approved training found on the Office of Research Services website.

8) Record Retention

Supervisors will retain all original disclosure forms in personnel files where conflict management plans are not required. Where conflict management plans are required the corresponding forms and management plan will be forwarded to the appropriate Dean or second level supervisor for approval and retention in permanent employee personnel file. A copy of all conflict management plans and training certifications will be forwarded to the Office of Research Services. All documents will be retained for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

9) Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty member, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

10) Public Accessibility

Prior to the expenditure of funds, the Institution will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

a) The Significant Financial Interest was disclosed and is still held by the Investigator;
b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.
11) Regulatory Authority

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

VII. Description of the Process and Appeals Procedures

Primary review and monitoring of activities related to conflict of interest and commitment will remain a function of the supervisor. Final approval resides with the next appropriate level supervisor. Annually, all EPA personnel will complete the annual report of potential conflict of interest activities or relationships. Questions on the annual report form are designed to identify activities that require additional oversight and review to insure that all activities are properly disclosed. Activities identified on the form should not necessarily be interpreted as prohibited; they may be permissible following their report, review, and approval. The employee and supervisor are to complete and sign the form. The form will be maintained in the employee's personnel file and no further action will be required if all questions are answered 'no'. Further reporting and review will be required for activities identified in the annual report. The employee should complete the additional disclosure forms A, B, or C as directed on the annual report explaining these activities. These additional forms will be reviewed by the supervisor with the employee and signed by both parties. Completed disclosure forms will be forwarded to the next appropriate level supervisor for final approval and a copy forwarded to the Office of Research Services. All forms will be maintained in the employee's personnel file. All employees required to file the Annual Report are also under a continuing obligation to update information in previous filings and make new filings at any time during the year should circumstances change.

If, after review by the appropriate person(s), disagreement exists between the employee and administration regarding the permissibility of activities, the employee may appeal the decision to the Conflict of Interest Review Committee. The appellant bears the burden of demonstrating that the proposed activity is not a conflict of interest as defined in this policy. Decisions by this committee will be final.

This document contains the policy statement of the UNC Board of Governors regarding conflicts of interest and commitment (300.2.2 as amended 06-15-12, the annual report, and additional necessary report forms as identified on the annual report (Forms A, B, and C).

VIII. Conflict of Interest Review Committee

This is a standing committee of the Chancellor made up of:

A. the Dean of the Graduate School and Research, who serves as permanent chair and is charged with receiving appeals, calling meetings of the committee, and reporting to appropriate persons/agencies (chancellor, provost, appropriate vice chancellors, deans
and department chairs, and where applicable UNC General Administration, NSF, HHS, or other federal funding agencies requiring such reports);

B. the chairperson or a representative from the UNCW Faculty Professional Relations Committee;

C. a faculty member with expertise in Business Law;

D. a representative from the Office of Human Resources; and

E. a tenured faculty member with academic credentials in the discipline of the person filing the appeal.

If the appeal involves a non-faculty EPA employee, the fifth member shall be a non-faculty EPA employee. If the appeal involves a member of the committee, directly or through a potential conflict of interest, the chancellor shall appoint a suitable substitute to replace that individual.

IX. Certification Statement

The following statement should appear, when required, in the cover letter submitted with applications for external funding:

There is in effect at UNCW a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought. Prior to the expenditure of any funds received under this award UNCW will notify the granting agency of the existence of any conflicting interest found by the University and assure that the interest has been managed, reduced or eliminated. For any interest identified as conflicting subsequent to the University's initial report under the award, the report will be made and the conflicting interest managed, reduced or eliminated, at least on an interim basis, within sixty days of that identification. UNCW agrees to make information available, upon request of the granting agency, regarding all conflicting interests identified by the University and how those interests have been managed, reduced or eliminated to protect the results of the work from bias.

X. Management of Conflicting Interests

The designated official(s) must review all financial disclosures and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the University to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the results of the work. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

A. Public disclosure of significant financial interests;
B. Monitoring of research by independent reviewers;

C. Modification of the research plan;

D. Disqualification from participation in all or a portion of the research;

E. Divestiture of significant financial interests; or

F. Severance of relationships that create actual or potential conflicts