

## Faculty Senate Resolution #09-50

Approved by the Faculty Senate: December 1, 2009

Approved by the Chancellor: pending

Approved by the Board of Trustees: pending

### Proposed revision to the *ECU Faculty Manual*, Appendix I. Policy on Conflicts of Interest and Commitment.

Proposed revisions are noted in **bold** print and deletions are noted in ~~strikethrough~~.

Additional suggested editorial revisions noted in red.

## APPENDIX I EAST CAROLINA UNIVERSITY POLICY ON CONFLICTS OF INTEREST AND COMMITMENT **AND EXTERNAL ACTIVITIES OF FACULTY AND OTHER PROFESSIONAL STAFF**

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## I. Introduction, **Applicability, and Responsibility for Compliance**

~~Effective July 1, 1995, all EPA faculty members and other professional Non faculty EPA staff of East Carolina University are subject to revised policies concerning conflicts of interest and conflicts of commitment affecting University employment and external professional activities. This policy covers full-time faculty and EPA non-faculty employees, part-time faculty and EPA non-faculty employees, (those UNC employees who are not subject to the State Personnel Act – hereinafter referred to as ‘EPA employees’). insofar as their University responsibilities are concerned, and faculty and EPA non-faculty employees who are on leave if the leave is funded at least partially from University sources. The revised ECU policies are~~ **This policy is based on policies and guidelines adopted by the UNC system Board of Governors, federal and state law, and federal agency sponsor requirements. Any questions regarding these procedures or the Board of Governors' policies upon which they are based should be directed to the appropriate divisional vice chancellor ECU Office of Research Compliance Administration.**

## II. The Concepts at Issue

~~The distinction between conflicts of interest and commitment is not always clear. In general, conflict of commitment relates to allocation of time and should become apparent in the annual review process conducted by the administrative superior. Conflict of interest involves matters which might unduly influence employee judgment in the conduct of employee affairs, such that personal financial advantage is or might be unduly gained.~~

~~More specifically, conflict of interest occurs when related personal considerations, e.g., employment of a spouse, potentially compromise the faculty or professional staff member's objectivity in fulfilling University duties or responsibilities, including research activities. Conflict of commitment occurs when the pursuit of outside activities involves an expenditure of time that potentially interferes with the faculty or professional staff member's obligations to students, to colleagues, and/or to the missions of the University.~~

## II. Definitions

- A. **Business** means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal **entity organized for profit, not-for-profit, or charitable purposes. "Business" excludes University-related entities, which is inclusive of the University, and any private medical practice or any other entity controlled by, controlling, or under common control with the University or with which the University has a contractual relationship for the purpose of providing patient care.**
- B. **Conflict of commitment** relates to an individual's distribution of effort between obligations to his or her University employment and participation in activities outside of University employment. The latter may include such generally encouraged extensions of professional expertise as professional consulting. A conflict of commitment occurs when the pursuit of such

**outside activities involves an inordinate investment of time that interferes with the EPA employee's obligations to students, to colleagues, and/or to missions of the University.**

- C. *Conflict of interest* relates to situations in which financial or other personal considerations may compromise, may involve the potential for compromising, or may have the appearance of compromising an EPA employee's objectivity in fulfilling University duties or responsibilities, including research activities.
- D. **"Executive Position"** refers to any position that includes responsibilities for a material segment of the operation or management of a business, including Board membership.
- E. **External professional activities for pay** means 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 EPA employee. Activities for pay not involving such professional knowledge, experience and abilities are not subject to advance disclosure and approval requirements of this Policy, although they are subject to the basic requirement that outside activities of any type not result in neglect of primary University duties, conflicts of interest, inappropriate uses of the University name or resources, or claims of University responsibility for the activity.
- F. **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 the president for the office of General Administration, for the purposes of implementing this policy.
- G. The **"Immediate Family"** of a faculty or EPA non-faculty employee includes his or her spouse, dependent children and/or other dependent(s) as defined in the Internal Revenue Code.
- H. **Inappropriate use or exploitation of University resources** means using any services, facilities, equipment, supplies, or personnel that members of the general public may not freely use. A person engaged in professional activities for pay may use, in that connection, his or her office and publicly accessible facilities such as University libraries; however, an office shall not be used as the site for compensated appointments with clients, e.g., for counseling or instruction. Under no circumstances may a supervisory employee use the services of a supervised employee during University employment time to advance the supervisor's external professional activities for pay.
- I. **"Participate"** means to be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, research collaborator or provider of direct patient care. The term 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) or, in the case of clinical research, to the trial participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

- J. ***Significant Financial Interest*** has the same meaning as in 42 C.F.R. 50.603 as it currently exists and as it may later be amended. This provision of the Code of Federal Regulations defines a Significant Financial Interest to mean: 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). The term does not include:
1. Salary, royalties, or other remuneration from the applicant institution;
  2. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program (SBIR);
  3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
  4. Income from service on advisory committees or review panels for public or nonprofit entities;
  5. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
  6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.
- K. ***"Sponsored Programs"*** means research, public service, training and instructional projects involving funds, materials, or other compensation from outside sources under grants, contracts, or cooperative agreements.
- L. ***"Technology"*** means any process, method, product, compound, drug, device, or any diagnostic, medical, or surgical procedure developed using University time, facilities, equipment, or funds whether intended for commercial use or not.
- M. ***University employment responsibilities*** include both "primary duties" and "secondary duties." Primary duties consist of assigned teaching, scholarship, research, institutional service requirements, and other assigned EPA employment duties. Secondary duties consist of professional affiliations and activities undertaken by EPA employees outside of the immediate University employment context that redound to the benefit of the profession and to higher education in general. Such endeavors, which may or may not entail the receipt of honoraria (See also 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; and service to accreditation bodies. Such integral manifestations of one's membership in a profession are encouraged, as extensions of University employment, so long as they do not interfere with the timely and effective performance of the individual's primary University duties.

The goal of this policy is to ensure that all potential conflicts of interest or commitment are disclosed so that appropriate administrative interventions may eliminate, avoid, or manage them. These policies, however, are not intended to limit responsible external activities.

### III. Policies

#### A. Conflict of Interest

~~It is the policy of the University that~~ faculty and EPA non-faculty **employees** shall avoid conflicts of interest that have the potential to affect adversely the University's interests, to compromise objectivity in carrying out University responsibilities, or otherwise to compromise the performance of University responsibilities. **compromise, may involve the potential for compromising, or may have the appearance of compromising the EPA employee's objectivity in fulfilling University responsibilities, including research activities.** Accordingly, outside activities and financial interests must be disclosed **by EPA employees** on an annual basis. Disclosures must be updated when new external interests develop. **This notwithstanding, EPA employees have a continuing obligation to timely update these disclosures as new external interests develop.** Outside activities and financial interests should be arranged to avoid such conflicts. Related policies are also discussed in the ECU Faculty Manual, Part VII. Research Information.

#### B. Conflict of Commitment

~~It is the policy of the University that~~ faculty and EPA non-faculty **employees** shall devote their primary professional loyalty, time, and energy to their teaching, research, service, and, where applicable, patient care at the University **employment responsibilities, including research activities.** ~~Accordingly,~~ outside activities and financial interests must be arranged to avoid interference with the primacy of these commitments. Policies and Procedures for those potential conflicts of commitment situations that do not involve conflict of interest are discussed in the ECU Faculty Manual, Part VI, General Personnel Information. The policy on External Professional Activities of Faculty and Other Professional Staff should be used for these potential conflicts of commitment ~~situations.~~ **Accordingly, EPA employees shall not engage in activities outside of their employment that involves an inordinate investment of time that interferes with the EPA employee's obligations to students, to colleagues, and/or to missions of the University. Such activities are unacceptable**

**outside activities. Conflicts of commitment may also arise in connection with non-compensated activities and a conflict of commitment may exist notwithstanding that an EPA employee received no economic benefit from the outside activity. The issue, in each case, is whether the employee is meeting the requirements of the job (as such responsibilities and requirements may be defined by applicable University policy and as may be further described in an individual's job description or appointment letter).**

**The policy on External Professional Activities of Faculty and Other Professional Staff should be used for these potential conflicts of commitment situations.**

**Although full-time faculty and other EPA employment is not amenable to precise, time-clock analysis and monitoring, administrators at the department and school levels are charged with the evaluation of the work of employees under their supervision. The formal occasions for determining whether an individual is devoting sufficient time and energy to University employment include regular reviews in connection with annual salary decisions and scheduled reviews incident to promotion, reappointment or tenure decisions and reviews of Notices of Intent to Engage in External Professional Activities for Pay.**

#### **IV. Categories and Examples of Potential Conflicts**

**Activities that may involve conflicts of interest can be categorized under four general headings:** ~~or commitment fall into three general categories that differentiate relationships according to potential for adverse impact.~~

**Category I: consists of activities that appear to involve a conflict of interest but in, fact, do not.** ~~consists of relationships that, while including some that are conflicts in a technical sense, are allowable because they do not compromise the objectivity of research results or other interests of the University, the sponsor, or the public. These relationships are generally minimal in their personal financial impact, and otherwise do not represent a potential source of bias.~~

**Category II: consist of activities that present potential conflict of interest and must be reported, but that may be allowable with administrative approval.** ~~consists of relationships that may be permissible following disclosure and, where necessary, the initiation of supervisory procedures designed to preclude bias or other inappropriate actions and to ensure the maintenance of academic standards and institutional integrity.~~

**Category III: consists of relationships that are generally not allowable because they involve potential conflicts of interest or they present obvious opportunities or inducements to favor personal interests over institutional interests. Before proceeding with such an endeavor, the EPA Employee must demonstrate that *in fact* his or her objectivity would not be affected and University interests otherwise would not be damaged. An approved conflict of interest management plan must be in place before any activities involving this category are initiated.**

~~consists of relationships that presumptively may be inappropriate for a faculty member or EPA non-faculty employee. In such cases, the individual must demonstrate to the University's satisfaction the compatibility of such practices with University policy prior to going forward with the proposed activity.~~

**Category IV: consists of activities that have the potential for creating conflicts of interest that are prohibited by North Carolina and/or federal law and, therefore, may not be undertaken.**

Provided below are representative, but not all-inclusive, examples of activities in each of these ~~three~~ **four** categories. Please refer to Section ~~IX below~~ **above** for important definitions.

Category I:

**Activities allowable, with no reporting required. The examples cited below involve activities external to University employment, and thus may present the appearance of a technical conflict, but they in fact do not have the potential for affecting the objectivity of the EPA employee's performance of University responsibilities; at most, some such situations could prompt questions about conflicts of commitment.**

- a) **An EPA Employee receiving royalties from the publication of scholarly works and other writings or for the licensure of patented inventions pursuant to the University's Patent and Copyright Policies (Faculty Manual, Part VII, Research Information).**
- b) **An EPA employee receiving nominal 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. Senior Academic and Administrative Officers may also be subject to special regulations regarding honoraria which require leave to be taken when external activities for pay will take place during the regular work week (UNC Policy Manual, 300.2.2.2[R]).**
- c) **An EPA Employee having an equity interest in a corporation used solely for the individual's consulting activities provided such consulting activities are appropriately reported and approved in accordance with the policy on, External Professional Activities of Faculty and Other Professional Staff and the corporation is not directly or indirectly conducting any business or sponsoring any projects with the University.**

**Category II:**

**Activities requiring disclosure for administrative review.**

**1. Research Activities**

- a) **An EPA 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.

b) Related persons working on the same funded or unfunded project.

## **2. External Activities**

a) An EPA Employee serving on the board of directors or scientific advisory board of an enterprise or business that provides financial support for University research, and the employee or a member of his or her immediate family may receive such financial support.

b) An EPA Employee serving in an executive position in a for-profit or not-for-profit business which conducts research or other activities in an area related to the University duties of the employee.

## **3. Ownership**

a) An EPA Employee having a financial interest or a significant financial interest in a business that competes with the services provided by the University.

b) An EPA Employee having significant equity or a Significant Financial Interest in a for-profit business which conducts research or other activities in an area related to the employee's University duties. An EPA 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.

## **4. Other**

a) An EPA employee receiving compensation or gratuities (other than occasional meals, gifts or desk copies of textbooks, and the like) from any individual or entity doing business with the University. This notwithstanding, see Category IV example (f).

b) Engaging in any other activity that has the potential for creating a conflict of interest or commitment as defined herein.

## **Category III:**

**Activities or relationships that are generally not allowable.**

### **1. Research Activities**

a) An EPA Employee participating in University research involving a technology owned by or contractually obligated (by license, option, or otherwise) to a business in which the individual or an immediate family member has a consulting relationship, has an ownership interest, or holds an executive position.

b) An EPA Employee participating in University research which is funded by a grant or contract from a business in which the individual or member of his or her immediate family has an ownership interest and/or significant financial interest;



- c) An EPA Employee assigning students, postdoctoral fellows or other trainees to University research projects sponsored by a business in which the individual or a member of his or her immediate family has an ownership interest and/or significant financial interest.

## 2. External Activities

- a) Assuming an executive position in a not-for-profit business with which the University has a contractual relationship known to the individual and which is engaged in commercial or research activities in a field related to the individual's University responsibilities.
- b) An EPA Employee making referrals of University business to an external business or company in which the individual or a member of his or her immediate family has a financial interest, including a consulting relationship.
- c) An EPA Employee associating his or her own name with the University in such way as to profit financially by trading on the reputation or goodwill of the University. An example of a context in which such an association might occur is external professional activity for pay. Mere identification of the University as the employer of the individual and of the individual's position at the University is permitted by this section, provided that such identification is not used in a manner that implies sponsorship or endorsement by the University.
- d) An EPA Employee serving as an expert witness for pay in litigation which requires the disclosure of research data in a manner that will compromise the University's or a student's ability to publish.

## 3. Public Disclosure

- a) An EPA Employee publishing or formally presenting University sponsored research results, or providing expert commentary on a subject, **without** simultaneously disclosing any significant financial interest relating to such results or such subject.
- b) An EPA Employee making unauthorized use of privileged information acquired in connection with one's University responsibilities. See also Category IV activities.

## 4. Administrative Responsibilities

- a) An EPA Employee taking administrative action in the course and scope of University responsibilities that is beneficial to a business in which the individual or an immediate family member has a significant financial interest, including a significant consulting relationship. See also Category IV activities.
- b) An EPA Employee influencing the negotiation of contracts between the University and an outside organization with which the individual or an immediate family member has a significant financial interest, including a significant consulting relationship. See also Category IV activities.

## 5. Committee Participation

- a) An EPA Employee serving on a committee of a governmental agency or private entity during the consideration by such a committee of the

regulation or application of a technology that is owned by or contractually obligated to a business in which that individual or immediate family has a significant financial interest, including a significant consulting relationship.

**Category IV: Activities that have the potential for creating conflicts of interest that are prohibited by North Carolina and federal law (including N.C. Gen. Stat. 14-234 and 14-234.1 as they currently exist and as may later be amended) and, therefore, may not be undertaken.**

- (a) N.C.G.S. (a1)(4) defines “direct benefit from a contract” to mean where a state officer or employee *or his or her spouse*: (i) has more than a ten percent (10%) ownership or other interest in an entity that is a party to contract with a state agency; (ii) derives any income or commission directly from the contract with a state agency; (iii) acquires any property under the contract with a state agency.**
- (b) N.C.G.S. 14-234 (a1)((2) states that a public officer or employee is involved in administering a contract if he or she oversees the performance of the contract or has authority to make decisions regarding the contract or to interpret the contract.**
- (c) N.C.G.S. 14-234 (a1)((3) states in part that a public officer or employee is involved in making a contract if he or she participates in the development of specifications or terms or in the preparation or award of the contract.**
- (d) North Carolina law prohibits a state officer or employee who is involved in making or administering a contract on behalf of a state agency from deriving a direct benefit from the contract (N.C.G.S. 14-234 (a)(1)).**
- (e) North Carolina law prohibits a state officer or employee who receives a direct benefit from a contract with the state agency he or she serves, but who is not involved in making or administering the contract, from attempting to influence any other person who is involved in making or administering the contract. (N.C.G.S. 14-234 (a)(2))**
- (f) North Carolina law prohibits a state officer or employee from soliciting or receiving any gift, reward, or promise of reward in exchange for recommending, influencing, or attempting to influence the award of a contract by the state agency he or she serves. (N.C.G.S. 14-234 (a)(3))**
- (g) *Contracts made in violation of N.C.G.S. 14-234 are void as a matter of law and anyone violating this statute may be prosecuted criminally.***
- (h) N.C.G.S. 14-234.1 prohibits a State officer or employee from benefiting financially, or helping someone else benefit, from non-public information gained by the employee in his or her official capacity. *Anyone violating this statute may be prosecuted criminally.***
- (i) *Note that the North Carolina Ethics Act (Ethics Act) also regulates Conflicts of Interest for “Covered Persons”. Questions regarding the Ethics Act should be directed to the University Attorney.***
- (j) *Medicare Anti-Kickback Law. The Medicare Anti-Kickback law (42 U.S.C. 1320a-7b(b)) prohibits compensation from research sponsors that provide***

or supply healthcare services or products to researcher-physicians or hospitals for their participation in clinical research if such compensation is intended to induce physicians or hospitals to purchase drugs or services of the research sponsor that will be paid by Medicare or Medicaid.

- (k) False Claims Act.** Researchers must certify in their grant applications that they are in compliance with statutory and regulatory requirements, including applicable statutes and regulations prohibiting conflicts of interest. Falsely certifying compliance could result in criminal prosecution and civil penalties under the False Claims Act (31 U.S.C. 3729, *et seq.*),

~~Activities that are routinely allowable and are not required to be disclosed pursuant to this policy.~~

- ~~d) Receiving royalties for published scholarly works and other writings or for inventions pursuant to the University's Patent and Copyright Policies (Faculty Manual, Part VII, Research Information).~~
- ~~e) 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; and service to accreditation bodies are permitted under the ECU Policy Statement on External Professional Activities of Faculty and other Professional Staff (Faculty Manual, Part VI, General Personnel Information) so long as they do not conflict or interfere with the timely performance of primary University duties. These activities are permitted even if they are performed for nominal honoraria or reimbursement of expenses, provided that the receipt of nominal honoraria or reimbursement of expense is not in conflict with any other applicable University, state, or federal policy, rule or regulation. These activities are not required to be disclosed in this Policy's Annual Faculty/Professional Staff Disclosure Form. However, a "Notice of Intent to Engage in External Professional Activity" may be required pursuant to ECU's policy (Faculty Manual, Part VI, General Personnel Information).~~
- ~~f) Ownership of or equity in a corporation used solely for the individual's consulting activities provided such consulting activities are appropriately reported and approved in accordance with Faculty Manual, Part VI, General Personnel Information, External Professional Activities of Faculty and Other Professional Staff.~~

**Category II:**

~~Activities that may be allowable following disclosure and, where necessary, the implementation of monitoring procedures.~~

**1. Research Activities**

- ~~e) Participating in University research (basic, applied, and clinical) on a technology developed by that individual or a member of his or her immediate family, unless the activity is specifically disallowed under the guidelines of Category III.~~
- ~~d) Participating in University research involving a technology owned by or contractually obligated (by license, option or otherwise) to a business in which the individual or immediate family has a consulting relationship.~~

- e) ~~Receiving through contract or gift University sponsored research support (whether in dollars or in kind) for research from a business in which the individual or immediate family has a consulting relationship.~~

## ~~2. External Activities~~

- c) ~~Serving on the board of directors or scientific advisory board of a business from which that individual or immediate family receives University sponsored research support or with which the University has a substantial contractual relationship known to the individual, unless the activity is specifically disallowed under the guidelines of Category III.~~
- d) ~~Assuming an executive position in a not-for-profit business with which the University has a substantial contractual relationship known to the individual and which is engaged in commercial or research activities in a field related to the individual's University responsibilities, unless the activity is specifically disallowed under the guidelines of Category III.~~

## ~~3. Ownership~~

- c) ~~Possessing a significant financial interest, including a significant consulting relationship, in a business that competes with the services provided by the University as a part of their academic, research, or service mission.~~
- d) ~~Possessing a significant financial interest, including a significant consulting relationship, in a business field related to the individual's University responsibilities, unless the activity is specifically disallowed under the guidelines of Category III.~~
- e) ~~Requiring or recommending one's own textbook or other teaching aids, materials, or equipment to be used in connection with University programs or those of immediate family. Such a requirement or recommendation must be preceded by disclosure and review according to this policy.~~

## ~~4. Other~~

- c) ~~Acceptance by the University employee or immediate family of other than nominal gratuities or special favors from one whom the individual knows is doing business with or proposing to do business with the University.~~
- d) ~~Engaging in any other activity that has the potential for creating a conflict of interest or commitment as defined herein.~~

## ~~Category III:~~

~~Activities that are presumptively not allowable. Many of the examples below may seem to overlap examples in Category II above; however, the addition of 'significant financial interests' in the activities below creates the presumption that these activities are not allowable.~~

### ~~1. Research Activities~~

- d) ~~Participating in University research involving a technology owned by or contractually obligated (by license, option, or otherwise) to a business in which the individual or immediate family holds significant stock or similar significant ownership interest, or has any other significant financial interest, other than a receipt of University sponsored research support, or receipt of royalties under University royalty sharing policies.~~
- e) ~~Receiving, through contract or grant, University sponsored research support (whether in dollars or in kind) for research from a business in which the~~

~~individual or immediate family holds a significant stock or similar significant ownership interest or has any other significant financial interest.~~

- ~~f) Assigning students, postdoctoral fellows or other trainees to University projects sponsored by a for-profit or not-for-profit business in which the individual or immediate family has a significant financial interest, including a significant consulting relationship.~~

## ~~2. External Activities~~

- ~~e) Assuming an executive position in a not-for-profit business with which the University has a substantial contractual relationship known to the individual and which is engaged in commercial or research activities in a field related to the individual's University responsibilities.~~
- ~~f) Making referrals of University business to an external business or professional office in which such individual or immediate family has a significant financial interest, including a significant consulting relationship.~~
- ~~g) Associating one's name or one's work with an external activity in such a way as to profit monetarily by trading on the reputation or good will of the University or to imply sponsorship or endorsement by the University. An example of a context in which such an association might occur is external professional activity for pay. Mere identification of the University as the employer of the individual and of the individual's position at the University is permitted by this section, provided that such identification is not used in a manner that implies sponsorship or endorsement by the University.~~

## ~~3. Public Disclosure~~

- ~~e) Publishing or formally presenting University sponsored research results, or providing expert commentary on a subject, with out simultaneously disclosing any significant financial interest relating to such results or such subject.~~
- ~~d) Unauthorized use of privileged information acquired in connection with one's University responsibilities to further one's own personal interests.~~

## ~~4. Administrative Responsibilities~~

- ~~e) Taking administrative action in the course and scope of University responsibilities that is beneficial to a business in which the individual or an immediate family member has a significant financial interest, including a significant consulting relationship.~~
- ~~d) Influencing the negotiation of contracts between the University and an outside organization with which the individual or an immediate family member has a significant financial interest, including a significant consulting relationship.~~

## ~~5. Committee Participation~~

- ~~b) Serving on a committee of a governmental agency or private entity during the consideration by such a committee of the regulation or application of a technology that is owned by or contractually obligated to a business in which that individual or immediate family has a significant financial interest, including a significant consulting relationship.~~

## V. Submission of Conflict Evaluation Forms (Disclosures). **COI Procedures**

~~Policy: Effective July 1, 1995, e~~Each faculty member and all other EPA **employee** will be required to disclose annually **relationships and circumstances that may raise**

**questions about conflicts of interest and conflicts of commitment relating to University employment responsibilities, including, but** ~~for both him/her selves and their immediate families (see definition in Section IX) the extent of their relevant external activities and relationships and their financial holdings that are related to the employee's university activities. These university activities include but are not limited to sponsored research activities. These external activities, relationships and financial holdings are described above in Section IV under Categories II & III. All potential Category II, III, and III IV relationships or financial holdings must be reported regardless of the dollar amounts involved. Category I activities and relationships are not required to be disclosed under this policy; however, other university reporting requirements may apply to these activities (see Section IV). Where there is some question whether an activity should be considered a Category I or II activity as described above, the faculty/EPA non-faculty eEmployee should include the activity in the disclosure for consideration by his/her supervisor.~~

~~All faculty and other EPA personnel are charged by the University to provide a full good faith disclosure. Failure to provide such a full disclosure may be considered a serious breach of this policy and may be cause for disciplinary action (see Section VIII).~~

Revisions or updates of the yearly disclosures are required between yearly disclosures whenever there is a significant change in the ~~faculty member's~~ EPA **employee's** or his/**her** immediate family's affairs that may lead to or may be perceived to lead to a conflict with the ~~faculty member's~~ **EPA employee's** university activities, e.g., the faculty member's spouse begins to receive consultant fees from a company that currently contracts with university for research services from the faculty member's laboratory.

Procedures: To facilitate disclosure and to ensure appropriate uniformity across the University, each individual will complete the "Annual Faculty/Professional Staff Disclosure Form." Each unit administrator will distribute this form annually to all faculty and professional staff (EPA non faculty) under his or her supervision and assure that completed forms are returned. **Unit Administrators shall summarize the disclosure completed by EPA employees to the Office of Research Compliance Administration.**

The purpose of this form is to identify employees' activities that may lead to actual or potential conflicts of commitment or interest so that appropriate administrative intervention may address the problems. The employee and the administrative ~~superior~~ **supervisor** are to complete and sign the annual disclosure form, which implies that the administrative ~~superior~~ **supervisor** has reviewed the form. No further action will be required if all questions are answered "no".

Further disclosure and review are required if questions elicit any "yes" responses on the Annual Faculty/Professional Staff Disclosure Form or on any mid-year revisions or updates of the annual form. The employee must then complete and sign the appropriate additional forms. Suggested provisions or plans for eliminating or managing conflicts

should be included in these additional forms where indicated. Examples of some (but not all) possible provisions for conflict management plans are:

1. Public disclosure of the significant financial interests or external activities;
2. Monitoring of activities by disinterested university officials to assure that conflicts do not arise;
3. Cessation of the pertinent outside activities;
4. Divestiture of the pertinent financial interests; **and**
5. Severance of the relationships that create actual or potential conflicts.

Since these forms have direct bearing on the employment of individuals with the University, all disclosure forms (the annual form and accompanying forms) and associated documents will be maintained in the administrative office of the employee's unit in his/her personnel folder for a period of at least three years following termination of the pertinent activities.

## **VI. Review and Approval of Activities and Plans for Eliminating or Managing Conflicts.**

The unit administrator (chair, dean, or the employee's supervisor in the case of a senior administrator) has the initial responsibility to review and approve or disapprove the disclosure forms filed with him or her by the EPA employees within that unit. The review shall follow the provisions of this Policy. The Unit administrator should be familiar with the definition of 'Significant Financial Interest' (~~See Section IX~~) to differentiate between Category II and Category III activities and relationships. Category III activities are presumptively considered to be non-allowable.

The unit administrator may refer any question regarding an annual disclosure form to the next higher administrative level for review and decision and must refer to the next higher level for review and approval all annual disclosures (and updates/revisions) which require additional forms (as described in the annual disclosure form) for EPA employees involvement in possible Category II and III activities as described above.

If a potential conflict is determined to exist, written plans for eliminating or managing the conflict will be developed in consultations between the employee, **the Office of Research Compliance Administration**, and his/her supervisors (**up to and including deans of academic units as appropriate**) and presented to the Vice Chancellor **of for Research and Graduate Studies** ~~of the appropriate division for concurrence~~. **For Category II through IV Conflicts of Interest, the plan will also be submitted to the appropriate division's Vice Chancellor for informational review.** It will then be presented to the ECU Research Ethics Oversight Committee (see below) for final approval. An adverse decision of the Committee to a proposed management plan may be appealed to the Chancellor. The supervisor of the EPA employee will be responsible for assuring the implementation and/or monitoring of the conflict management plan.

Documentation of all decisions on activities and associated conflict management plans will be maintained in the employee's personnel folder.

In order to fulfill the certification requirements of grant and contract funding agencies (e.g., the NIH and NSF), each unit administrator shall also provide annually to the Vice Chancellor for Research and Graduate Studies a list of all faculty members and EPA staff in the administrator's unit who have submitted approved current annual disclosure forms and, where needed, an indication when such approval required development of an acceptable conflict management plan. This list may be amended as needed during the year. The Vice Chancellor for Research **and Graduate Studies** or **his** designee will use this information to **report any perceived or potential COI to the sponsor or to certify to potential funding agencies that this Institution has a conflict of interest policy consistent with NIH and NSF guidelines and that to the best of our knowledge all provisions of the policy have been followed with respect to proposals submitted to the agencies by ECU faculty and staff.**

If after initial review **of any disclosure** by the department head, dean, and vice chancellor, questions remain regarding ethical issues or if disagreement exists between the EPA employee and the administration regarding the permissibility of activities, **or if the COI management involves more than disclosure and minor oversight**, the situation may be referred to a faculty/administrative advisory committee for review of conflicts of interest and commitment. This committee, the *Research Ethics Oversight Committee*, will be chaired by the Vice Chancellor for Research & Graduate Studies. **Appropriate individuals will be appointed members to the committee by the Vice Chancellor for Research and Graduate Studies.** ~~and will have representatives from the faculty senate as members.~~ When the committee reviews conflict management plans, a representative of university attorney's office shall be present. ~~In addition, when a management plan involves graduate students, a representative from the graduate council will also be present. Other appropriate individuals will be appointed members to the committee by the Vice Chancellor for Research & Graduate Studies.~~ Decisions by this committee will be presented to the Chancellor for his or her concurrence and, if approved, will become the University's final position **subject only to appeal in accordance with Section 501C(4) of The Code of the University of North Carolina.**

If the activity at issue involves external support (grant, contract or cooperative agreement), the ~~vice chancellor for research~~ **Director of Sponsored Programs** shall inform the sponsor **in accordance to Sponsor policy and guidelines of the COI.** ~~whenever the University determines that it is unable to develop a satisfactory conflict management plan for an actual or potential conflict of interest.~~

Whenever human subjects are involved in an activity presented to the ~~Research Ethics Oversight Committee~~ **University's Office of Research Compliance Administration** (including approvals of conflict management plans), the University & Medical Center Institutional Review Board (UMCIRB) will be confidentially notified of the issue and the Committee's actions.

## VII. Institutional Conflict of Interest



East Carolina University, from time to time, forms relationships with profit-making entities (including the holding of equity interests) for mutual benefit. However, such relationships may put the University into actual or apparent conflict of interest situations when accepting grants or contracts from the profit making entities for research or other activities. (See exclusion at the end of this section for certain types of relationships.) To assure that these grants and contracts are performed with the highest level of integrity by University employees and to assure that the public maintains its trust in University activities, the following procedures shall be followed:

1. At the beginning of each calendar year, the Director, Office of Technology Transfer shall prepare a disclosure listing all profit-making entities in which the University has a significant financial interest (~~See Section IX.4~~). This disclosure shall be updated during the year as new relations develop and old ones terminate. This disclosure and its updates will be submitted to the Vice Chancellor for Research and Graduate Studies who shall distribute the disclosure to the Chancellor, the other Vice Chancellors and Deans, and the Research Ethics Oversight Committee. Copies of the disclosure and updates shall also be distributed to those university administrative offices charged with approving and administering grants and contracts and **other regulatory committees** ~~human subjects research protection~~ (**for example**, Office of Sponsored Programs, Office of Grants and Contracts Administration and the UMCIRB).
2. Units submitting proposals for external funding to commercial entities may not be aware of possible institutional conflict of interest issues. Thus, the Office of Sponsored Programs shall have the primary responsibility of notifying **Office of Research Compliance Administration**, Vice Chancellor for Research and Graduate Studies and the submitting unit of the University's conflict of interest as part of its regular procedures for the review and approval of such applications. The **Office of Research Compliance Administration or the** Vice Chancellor or his designee shall then develop a plan to manage the institutional conflict of interest after consultation with the submitting unit and other relevant university offices. The conflict management plan shall be submitted to the Research Ethics Oversight Committee for review. The Committee may approve the plan (with or without mandatory changes) or disapprove the plan. University acceptance of grants and contracts related to a management plan is contingent upon approval of the management plan by the Committee. A negative decision of the Committee may be appealed to the Chancellor. An institutional conflict management plan may range from a simple disclosure of the University's interest in publications and reports emanating from the grant or contract to complete University divestiture of the financial interest. The institutional conflict of management plan shall be separate from and in addition to any conflict management plans for conflicts of interests of individuals (e.g., the principal investigator) involved in the grant or contract.
3. When considering an institutional conflict of interest management plan, the Research Ethics Oversight Committee shall a) include as voting members, one or more individuals from the general public who have no direct or indirect relationship with the University, i.e., the individuals and their spouses or other dependents must not be current employees or students of the University; and b) recuse from the deliberations of the Committee any ECU member of the Committee who has been

involved in the negotiation, approval, or implementation of the relationship that is the basis of the actual or perceived conflict of interest. The general public members of the Committee should be individuals that have sufficient education or experience to understand both the issues before the Committee and the possible impacts of the Committee's decisions on the general public.

4. Arrangements for plan implementation and oversight shall explicitly be part of an institutional conflict management plan. Implementation and oversight will usually be the joint responsibility of the submitting unit and the Office of the Vice Chancellor for Research and Graduate Studies. However, other arrangements shall be made for plan implementation and oversight if, in the judgment of the Research Ethics Oversight Committee, such arrangements are necessary for the effective management of the conflict.

Excluded Relationships: A relationship with a profit making organization for the purposes of this institutional conflict of interest policy shall not include ordinary investments of the university's endowment that are managed by the Board of Trustees of the Endowment Fund or ordinary client-vender relationships where the University contracts for specific goods or services from a profit-making organization.

### **VIII. External Professional Activity for Pay Procedures**

**1. An EPA Employee who plans to engage in external professional activity for pay shall complete the "Notice of Intent to Engage in External Professional Activity for Pay" (hereinafter referred to as "Notice of Intent") in a format as described in section 2 of this Part VIII. The Notice of Intent shall be filed with the head of the department in which the individual is employed. A separate "Notice of Intent" shall be filed for each such activity in which an employee proposes to engage. Unless there are exceptional circumstances, the "Notice of Intent" shall be filed not less than ten (10) calendar days before the date the proposed external professional activity for pay is to begin.**

**2. The Notice of Intent Format: The format for giving notice of Intent should follow the sample notice form.**

~~NOTICE OF INTENT TO ENGAGE IN EXTERNAL PROFESSIONAL ACTIVITIES FOR PAY~~

Date: \_\_\_\_\_

\_\_\_\_\_(Name) intends to engage in external professional activity for pay under the following conditions:

1. — Name and address of contracting organization;
2. — Nature of proposed activity;
3. — Beginning date and anticipated duration of activity;

4. ~~On average, how many hours per week will be devoted to this activity?~~
- a. ~~For twelve-month employees, for the anticipated duration of the activity, within the current fiscal year ending June 30:~~  
~~\_\_\_\_\_;~~
- b. ~~For 9-month employees, for each component part of the academic year, as applicable, within the current fiscal year ending June 30:~~
- i. ~~Second summer session (post July 1) \_\_\_\_\_~~
- ii. ~~Fall Semester \_\_\_\_\_~~
- iii. ~~Spring Semester \_\_\_\_\_~~
- iv. ~~First Summer Session (pre July 1) \_\_\_\_\_~~

5. ~~Total number of hours to be devoted to activity: \_\_\_\_\_~~

6. ~~Identify any classes, meetings, or other university duties that will be missed because of involvement in the proposed activity (respond separately for each applicable component part of the academic calendar if 9-month employee) and state what arrangements have been made to cover any such duties;~~

~~Duties Missed \_\_\_\_\_ Arrangements to Cover \_\_\_\_\_~~

~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~

7. ~~Use of University resources in connection with proposed activity:~~

1. ~~Will the activity entail the use of any university resources? (see Section II(G) above and UNC Policy Manual, 300.2.2, Section I, Item G) \_\_\_\_\_ Yes \_\_\_\_\_ No~~

2. ~~If yes, describe what resources will be used;~~

~~\_\_\_\_\_~~  
~~\_\_\_\_\_~~

8. ~~To your knowledge, does the contracting organization provide funding which directly supports any of your University duties or activities?: Yes()~~

~~No()~~~~To be completed if the contracting organization is a private firm:~~

a. ~~Do you or any member of your immediate family own an equity interest in the contracting organization: Yes() No ()~~

b. ~~Do you hold an office in the contracting organization? Yes() No ()~~

9. ~~Performance of the above described activity is consistent with the Board of Governors Policy on Conflicts of Interest and Commitment and External Professional Activities~~

~~Signatures follow..~~

10. ~~Each EPA faculty and EPA non-faculty participating in external activity for pay must report the activity during the past fiscal year. Such reports (a sample form for reporting external activity for pay is available at the~~

~~Academic Affairs's webpage) will contain the following information for each external professional activity for pay engaged in during the last fiscal year preceding the date of filing of a "Notice of Intent":~~

- ~~11. Contracting organization;~~
  - ~~12. Beginning and ending date of activity (if completed); 3. Average hours per week devoted to this activity;~~
  - ~~13. Total number of hours devoted to this activity;~~
  - ~~14. Nature of professional activity;~~
  - ~~15. Date Notice of Intent was filed; and~~
  - ~~16. Administrative Action on Notice of Intent which will have the following signatures and information:~~
  - ~~17. Signature and date of unit head certifying activity determined to be consistent with university policy;~~
  - ~~18. Other action (as required);~~
  - ~~19. Signature and date of Dean or Other Administrative Officer (Approval by dean or next higher administrator is required if the contracting organization is providing funding to the University or if a family member or the EPA faculty or EPA non faculty owns equity or hold an office in the contracting organization) if activity determined not to be consistent with university policy;~~
  - ~~20. Action on appeal (if any) and date action taken;~~
  - ~~21. Signature and date of Dean or next higher administrator if appealed; and~~
  - ~~22. Signature of Chancellor if appealed.~~
- ~~23. Any administrative action approving a "Notice of Intent" shall be effective only for the remaining balance of the fiscal year (in the case of twelve-month employees) or for the balance of the academic year (for nine-month employees).~~

**3. Approval of a "Notice of Intent" may be granted for a period not to exceed the balance of either 1) the fiscal year (in the case of twelve-month employees and employees with contract service periods that include the summer session) or 2) the academic year (in the case of nine (9) month employees with no summer session contract period) remaining as of the date of approval; if the approved activity will continue beyond the end of the relevant fiscal or academic year in which it was begun, an additional "Notice of Intent" must be filed at least ten days before engaging in such activity in the succeeding relevant year.**

**4. Except as set out in paragraph 5 below, the "Notice of Intent" shall be considered as follows: If, after a review of the "Notice of Intent" and consultation with the EPA employee, the unit head determines that the proposed activity is not consistent with this policy statement of the Board of Governors and East Carolina University, the EPA Employee shall be notified of that determination within ten (10) calendar days of the date the**

**"Notice of Intent" is filed. In the event of such notification by the unit head, the EPA Employee shall not proceed with the proposed activity but may appeal that decision to the next higher administrator and then to the Chancellor or the Chancellor's designee. A decision on any such appeal shall be given to the EPA Employee within ten calendar days of the date on which the appeal is received. The decision of the Chancellor is final. Appeals shall be made in writing on the "Notice of Intent" form.**

**5.If question 8, question 9a, or question 9b on the Notice of Intent, above, is answered in the affirmative the procedure set out in paragraph 4 above shall be modified as follows: The decision of the unit head to approve the activity shall be reviewed promptly and approved or disapproved within ten (10) days of receipt by the next higher administrator, and appeal of a disapproval by that officer shall be to the Chancellor or the Chancellor's designee. In addition, the Vice Chancellor for Research and Graduate Studies must review the external activity for management of any Conflicts of Interest and notify the University and Medical Center Institutional Review Board if the EPA Employee is participating in a protocol involving human subjects at ECU to ensure compliance with applicable IRB laws and regulations.**

**6.Departmental summaries of all "Notices of Intent" filed and of actions taken in response to such "Notices of Intent" during the preceding fiscal year shall be submitted by unit heads to the Chancellor each July. As initiated by the UNC General Administration on or before September 1 of each year, the Chancellor will provide an annual summary report to the President.**

**7.If the external professional activity for pay is wholly performed and completed outside of the academic year by EPA employees serving on academic year contracts, said EPA Employees do not need to file Notices of Intent with their unit head provided that the activity does not conflict with this policy statement of East Carolina University and of the Board of Governors and is not conducted concurrently with a contract service period for teaching, research, or other services to East Carolina University during a summer session.**

**8.University employees not complying with these procedures will be subject to disciplinary action. Unit heads are held responsible for proper reporting.**

### **III IX. Enforcement of the Policies**

~~Faculty and non-faculty~~ **EPA Employees** staff are under a clear obligation to adhere to the ECU policies and procedures to disclose and to remove or appropriately manage conflicts of interest or commitment. Breaches of the policy/procedures will be viewed as serious ethical violations by the persons involved. Possible breaches of the policy/procedure include, but are not limited to:

1. Furnishing false, misleading or incomplete information on the disclosure forms;
2. Failure to promptly update disclosure forms before the required annual update when a significant change in a person's financial or fiduciary status places the individual into an immediate potential conflict of interest or commitment situation;
3. Failure to comply with the procedures described above (e.g., refusal to respond to inquiries, responding with incomplete or knowingly inaccurate information, or otherwise);
4. Failure to remedy conflicts as determined by the Procedures; and
5. Failure to comply with a prescribed monitoring plan.

If a possible breach in the policy/procedures occurs, the appropriate dean shall consult with the faculty person and his chair. If no resolution is forthcoming, the dean shall refer the case to the appropriate vice chancellor. The vice chancellor shall consult with the vice chancellor for research and shall initiate an investigation and/or hearing as prescribed in Faculty Manual, Part VII and Appendix D and apply sanctions as determined by university policies. Such sanctions may range from administrative intervention to dismissal from employment, all in accordance with applicable university policies.

#### ~~IX. Definitions~~

- ~~1. "Business" means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes. "Business" excludes University-related entities, which is inclusive of the University, and any private medical practice or any other entity controlled by, controlling, or under common control with the University or with which the University has a contractual relationship for the purpose of providing patient care.~~
- ~~2. "Executive Position" refers to any position that includes responsibilities for a material segment of the operation or management of a business, including Board membership.~~
- ~~3. The "Immediate Family" of a faculty or EPA non-faculty employee includes his or her spouse, dependent children and/or other dependent(s) as defined in the Internal Revenue Code.~~
- ~~4. "Significant 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, license agreements, and royalties from such rights). The term does not include:~~
  - ~~(1) Salary, royalties, or other remuneration from East Carolina University to its faculty or staff;~~
  - ~~(2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;~~
  - ~~(3) Income from service on advisory committees or review panels for public or nonprofit entities;~~
  - ~~(4) An equity interest that when aggregated for the faculty/staff and the faculty/staff's immediate family, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;~~

- (5) ~~Salary, royalties or other payments that when aggregated for the faculty/staff and the faculty/staff's immediate family over the next twelve months, are not expected to exceed \$10,000 from any one source.~~
- (6) ~~Mutual, pension, investment or other funds over which the employee or the University does not exercise direct control.~~
5. ~~"Participate" means to be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, research collaborator or provider of direct patient care. The term 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) or, in the case of clinical research, to the trial participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.~~
6. ~~"Sponsored Programs" means research, public service, training and instructional projects involving funds, materials, or other compensation from outside sources under grants, contracts, or cooperative agreements.~~
7. ~~"Technology" means any process, method, product, compound, drug, device, or any diagnostic, medical, or surgical procedure developed using University time, facilities, equipment, or funds whether intended for commercial use or not.~~

Example Forms A-E are available online at

<http://www.ecu.edu/cs-acad/fsonline/customcf/facultymanual/appendixi/appendixi.htm>