POL 05.45.01

Policy on Conflicts of Commitment and Interest Affecting University Employment

Authority: Chancellor

History:

• First Issued: June, 1995

• Revised: December 18, 2012 and August 2, 2013

• Last Revised: November 17, 2020

Related Policies:

- <u>UNC Policy Manual 300.2.2 Conflicts of Interest and Commitment Affecting Faculty and Non-Faculty EHRA Employees</u>
- UNC Policy Manual 300.2.2 [G] Guidelines on Implementing the UNC Conflict of Interest and Commitment Policy
- UNC Policy Manual 300.2.2.1[R] External Professional Activities for Pay by Faculty and Non-Faculty EHRA Employees
- <u>UNC Policy Manual 300.2.2.2[R] Regulations for Senior Academic and Administrative</u> Officers on External Professional Activities for Pay and Honoraria
- <u>UNC Policy Manual 500.1 University Research Relations with Government Agencies</u> and Private Entities
- UNC Policy Manual 500.2 Patent and Copyright Policies
- UNC Policy Manual 500.6 University Equity Acquisition Policy
- Office of State Human Resources Employment and Records: Secondary Employment

Additional References:

- U.S. Public Health Service Financial Conflicts of Interest (FCOI) Revised Final Rule, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F)
- N.C.G.S. §14-234 Public officers or employees benefiting from public contracts; exceptions
- Notice of Intent to Engage in External Professional Activities for Pay
- <u>UNC System Office Guidelines Concerning Use of University of North Carolina</u> Resources for Political Campaign Activities
- N.C.G.S. §126-4 Powers and duties of State Personnel Commission
- N.C.G.S. §126 North Carolina Human Resources Act
- Administrative Rule 25 NCAC 01C.0700
- Secondary Employment Form
- Report of Non University Activities
- 20U.S. Code §1001(a) General definition of Institution of Higher Education
- UNCP Faculty Handbook

Contact Info: Associate Vice Chancellor for Academic Planning and Accreditation, (910) 521-6180; Director of Sponsored Research and Programs (910) 521-6357

1. INTRODUCTION

- 1.1 The University of North Carolina at Pembroke policy concerning Conflicts of Commitment and Interest Affecting University Employment supports the policies and guidelines adopted by the UNC Board of Governors on June 15 and June 21, 2012. The University of North Carolina at Pembroke (UNC Pembroke) subscribes to the statement of *The Code* of The University of North Carolina indicating that the basic mission of the faculty is "the transmission and advancement of knowledge and understanding." University faculty engage in a number of activities within the academy related to their teaching, research, and service. In addition, because of the nature of their credentials and expertise, EHRA faculty members and non-faculty employees also have opportunities to utilize their skills and knowledge in settings and activities outside the university. In most instances, this independence and flexibility work to the advantage and benefit of the employee, the institution, and the community. The same opportunities can become problems, however, when a conflict of commitment or a conflict of interest arises. The policies and procedures outlined in this document are designed to prevent circumstances that can limit and/or adversely affect the performance of university duties.
- 1.2 It is the policy of The University of North Carolina at Pembroke 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. The Conflicts of Commitment and Interest Affecting University Employment Policy is in compliance with the U.S. Public Health Service Financial Conflicts of Interest (FCOI) Revised Final Rule, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, which was issued August 25, 2011 (42 CFR Part 50 Subpart F).

2. SCOPE

2.1 This policy applies to all Covered Employees (EHRA employees, including faculty, non-faculty, and designated SHRA employees who are paid with sponsored research funds), students, visiting scientists or scholars, or trainees. Senior academic and administrative officers are also subject to Section 300.2.2.2[R] of the UNC Board of Governors' Policy Manual on "Regulations for Senior Academic and Administrative Officers on External Professional Activities for Pay and Honoraria." This policy also applies to any individual, regardless of employment type or status, involved in federally funded research including the design, conduct, or reporting of such research. When university research is funded by an external sponsor, including a federal government agency, such as the Public Health Service (PHS) or the National Science Foundation (NSF), a conflict of interest disclosure is required prior to the submission of the research proposal to the agency and any conflict must be eliminated or managed prior to the disbursement of federal funds. For Public Health Service (PHS) or the National Science Foundation (NSF) funded research, this policy also applies to external investigators (i.e., sub-awardee recipients, collaborators, consultants, etc.) who are key personnel.

3. DEFINITIONS

- 3.1 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. A conflict of commitment arises when an individual's activities outside the university interfere with the performance of responsibilities within the institution. The latter may include such generally encouraged extension of professional expertise as professional consulting.
- 3.2 Conflict of interest arises when financial or other personal considerations, circumstances, or relationships may compromise, involve the potential for compromising, or have the appearance of compromising a faculty member's objectivity in meeting university duties or responsibilities, including research activities. The biases resulting from conflicts of interest may compromise such responsibilities as making decisions about personnel and purchases; selecting instructional materials for classroom use; gathering, analyzing, and interpreting data; sharing research results; selecting research protocols; employing statistical methods; and mentoring and judging student work. A conflict of interest exists when a Covered Employee or any member of that person's immediate family (spouse and dependent children) has a personal interest in an activity that could have an impact on decision making at the university with respect to teaching, research, or administration. 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.
- 3.3 Department means an academic department or any other administrative unit designated by the chancellor of the university for the purposes of implementing this policy. Department chair or department head refers to the person with supervisory responsibility for the Covered employee, whether in an academic department or non-academic department or administrative unit.
- 3.4 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 Covered employee.
- 3.5 University employment responsibilities include both "primary duties" and "secondary duties" on behalf of the institution. Primary duties consist of assigned teaching, scholarship, research, institutional service requirements, and other assigned employment duties. Secondary duties consist of professional affiliations and activities traditionally undertaken by Covered Employees outside of the immediate university employment context that benefit the profession and higher education in general. Such endeavors, which may or may not entail the receipt of honoraria 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 conflict or interfere with the timely and effective performance of the individual's primary duties.

- 3.6 Covered Employee refers to any person –including EHRA faculty, EHRA non-faculty, and designated SHRA employees who are paid with sponsored research funds who is employed by UNC Pembroke; or any individual, regardless of employment type or status, involved in federally funded research including the design, conduct, or reporting of such research.
- 3.7 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 entity (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 provisions of this policy.
- 3.8 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 university 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 university policy. Under no circumstances may any employee use the services of another employee during university employment time to advance the externally compensated employee's activities for pay.
- 3.9 Annual disclosure means the disclosure of any Conflicts of Interest and/or Conflicts of Commitment that must be completed by all Covered Employees each year by October 1st. The annual disclosure must be completed even if the Covered Employee has anything to disclose. The annual disclosure covers current activities and interests, and those from the previous twelve (12) months, and must be updated within thirty (30) days of discovering a new reportable financial interest or activity.
- 3.10 PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated. Components include, but not limited to, the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA).
- 3.11 Research funded by PHS means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development.

- 3.12 Investigator means the project director or principal investigator and all key personnel for a research project. For PHS-funded research, the investigator shall include any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding, which may include, for example, collaborators, consultants, or post-doctoral fellows.
- 3.13 Significant Financial Interest (SFI), as defined by the PHS FCOI Revised Final Rule (2011), refers to one or more of the following interests of the employee (and those of his/her spouse and dependent children) that reasonably appear to be related to the employee's institutional employment responsibilities:
- 3.13.1. With regard to any publicly traded entity, an SFI exists if the value of the remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, is \$5,000 or more (see sections 6.2.10.2.1 and 6.6.2 for monitory threshold associated with federally funded grants). 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;
- 3.13.2. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, is \$5,000 or more, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (regardless of value) (e.g., stock, stock option, or other ownership interest); or
- 3.13.3 An SFI exists with respect to any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests by the Covered Employee or his/her immediate family.
- 3.13.3.1 For PHS-funded investigators only, SFIs also include reimbursed or sponsored travel related to their institutional responsibilities except for excluded sources of funds.
- 3.13.3.2 For PHS-funded research, SFI does not include the following types of financial interests:
- 3.13.3.2.1 salary, royalties, or other remuneration paid by the university to the Covered Employee if the Covered Employee is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
- 3.13.3.2.2 income from investment vehicles, such as mutual funds and retirement accounts, as long as neither the Covered Employee nor any member of the Covered Employee's immediate family directly controls the investment decisions made in these vehicles;

- 3.13.3.2.3 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;
- 3.13.3.2.4 income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- 3.13.3.2.5 travel that is reimbursed or 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 of higher education that is affiliated with an institution of higher education.
- 3.14 Financial Conflicts of Interest (FCOI) exist when the university, through its designated official(s), reasonably determines that an investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. It is the institution's responsibility to determine whether an SFI relates to the employee's PHS-funded research and represents a FCOI.

4. POLICIES ON CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST

4.1 Conflict of Commitment

4.1.1 It is the policy of UNC Pembroke that faculty shall devote their primary professional loyalty, time, and efforts to teaching, research, and service and related duties and that non-faculty employees shall devote their primary professional loyalty, time, and efforts to the specific requirements of their university employment. Therefore, in accord with this policy, outside activities and financial interests must not interfere with carrying out university employment responsibilities. See UNC Policy Manual 300.2.2 - Conflicts of Interest and Commitment Affecting Faculty and Non-Faculty EHRA Employees.

4.2 Conflict of Interest

- 4.2.1 It is the policy of UNC Pembroke that Covered Employees will avoid conflicts of interest that may adversely affect the university's interests, compromise objectivity in conducting research, or compromise their performance of university responsibilities. Thus, external activities and financial interests must be arranged to avoid such conflicts.
- 4.2.2 It is the policy of UNC Pembroke to comply with the rules applicable to federally funded projects for all externally funded research conducted at the university. Federal funding agencies require that the university manage, reduce, or eliminate any actual or potential conflicts of interest that may exist in relation to instruction, research, and service activities funded by the federal government. It is the purpose of this policy to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and

reporting of externally funded research will be free from bias resulting from investigator financial conflicts of interest.

5. CATEGORIES OF ACTIVITIES WITH POTENTIAL FOR CONFLICT OF INTEREST

- 5.1 Activities that may involve financial conflicts of interest may be categorized under four (4)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.
- 5.2 Category I: Activities that are allowable and are disclosed. Category I includes activities external to university employment which may present the appearance of a technical conflict, but have little or no potential for affecting the objectivity of the Covered Employee's performance of university employment responsibilities. At most, some such situations could prompt questions about Conflicts of Commitment. Examples include:
- 5.2.1 A Covered Employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the UNC Pembroke Policies.
- 5.2.2 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. EHRA employees must comply with UNC Policy Manual, <a href="Section 300.2.2.1[R]. Senior academic and administrative officers are subject to special regulations regarding honoraria and must comply with UNC Policy Manual, <a href="Section 300.2.2.2[R].
- 5.3 Category II: Activities requiring disclosure for further administrative review and analysis because of potential for conflict. Category II activities are those which 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. Examples are presented here as clarification of the nature of conflict of interest.
- 5.3.1. A Covered Employee requiring students to purchase the textbook or related instructional materials of the employee or members of his or her immediate family, that produces compensation for the employee or family member.
- 5.3.2 A Covered Employee receiving compensation or gratuities from any individual or entity doing business with the university.
- 5.3.3. A Covered Employee serving on the board of directors or scientific advisory board of an enterprise that provides financial support for university research and from which the employee or a member of his or her immediate family may receive such financial support.

- 5.3.4 A Covered 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 other university duties of the employee.
- 5.3.5 A Covered Employee having a financial interest in a business that competes with services provided by the university. Note that, under <u>North Carolina state law</u>, 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.
- 5.3.6 A Covered Employee or an immediate family member having an equity or ownership interest in a publicly or non-publicly traded entity or enterprise.
- 5.3.7 A Covered Employee accepting support for university research under conditions that require research results to be held confidential, unpublished, or 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 university policies on intellectual property.
- 5.3.8 A Covered Employee accepting research support or income that is paid from all other sources, including private entities, foreign governments, foreign universities, non-profits, or Non-Governmental Organizations (NGO); or
- 5.3.9 A Covered Employee accepting reimbursement or sponsored travel from all other sources, including private entities, foreign governments, foreign universities, non-profits, or Non-Governmental Organizations (NGO).
- 5.4 Category III: Activities generally not allowable or permitted unless an approved conflict of interest management plan is in place. Activities in Category III generally are not permissible because they involve actual or potential financial conflicts of interest or present obvious opportunities or inducements to favor personal interests over institutional interests. Before proceeding with such an activity, the Covered Employee must demonstrate that his or her objectivity would not be affected and university interests would not be damaged and an approved conflict of interest management plan is in place.
- 5.4.1 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) the Covered Employee or entity in which the individual or an immediate family member has a consulting relationship, has an equity or ownership interest, or holds an executive position.
- 5.4.2 A Covered Employee participating in university research which is funded by a grant or contract from an enterprise or entity in which the Covered Employee or an immediate family member has an equity or ownership interest.

- 5.4.3 A Covered Employee assigning students, post-doctoral fellows or other trainees to university research projects sponsored by an enterprise or entity in which the Covered Employee or an immediate family member has an equity or ownership interest.
- 5.5 Category IV: Activities that are not allowable under any circumstances.
- 5.5.1 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.
- 5.5.2 A Covered Employee associating his or her own name with the university in such a way as to profit financially by trading the reputation or goodwill of the university.
- 5.5.3 A Covered Employee making unauthorized use of privileged information acquired in connection with his or her university responsibilities.
- 5.5.4 A Covered Employee signing agreements that assign university patent and other intellectual property rights to third parties without prior university approval.
- 5.5.5 A Covered Employee engaging in any other activity otherwise prohibited by law or university policy.

6. CONFLICT OF INTEREST DISCLOSURE, REVIEW AND MONITORING PROCEDURES

- 6.1 Avoiding Conflicts of Interest
- 6.1.1 At UNC Pembroke, conflict of commitment and/or interest is generally discovered and resolved through: 1) the normal expectations and routine monitoring of faculty and staff performance; 2) the required External Professional Activities for Pay reporting process; 3) reports by and interactions with colleagues, department chairs, and administrators in the process of consideration for tenure and/or promotion and merit pay; and 4) the process of applying for external research funding or IRB approval. In an attempt to avoid and forestall conflicts of interest, UNC Pembroke will follow the procedures described below.
- 6.2 Disclosure, Review, and Monitoring Requirements
- 6.2.1 Requirement of Disclosure: The responsibility for compliance with the law, policy, and regulations on conflict of interest and commitment resides both with the individual Covered Employee and the university. The Covered Employee is required to disclose and the university will review all related financial interests, regardless of monetary amount, in order to determine if a Significant Financial Interest (SFI) exists. Annual Disclosures are required at the beginning of each academic year, each Covered employee is required to submit a Conflict of Interest Disclosure Form that discloses potential conflicts of interest during the upcoming academic year. This form is submitted in addition to the form on External Professional Activities for pay. The obligation to disclose potential conflicts of interest is not negated by the filing of a Notice of Intent to Engage in External Professional Activities for Pay. Updated forms must be submitted

during the year if changes occur which may involve a potential conflict of interest, which eliminate a previously discussed conflict of interest, or which change any responses on the previously filed disclosure form. The supplemental form must be submitted at least thirty (30) days before the date of a new activity that may give rise to a conflict of interest.

- 6.2.2 It is the responsibility of the Office of Academic Affairs and/or the Office of Human Resources to initiate the disclosure process in the fall of the academic year. Covered Employees will be encouraged to seek assistance from their department chair, director of their administrative department, or the university general counsel if questions arise.
- 6.2.3 All disclosure forms will be on file in the Covered Employee's personnel file and will be considered confidential. The information disclosed on the forms will be made available only to individuals duly charged with the responsibility for review and will be released only in accordance with and as required by North Carolina law or lawful court order.
- 6.2.4 The department chair or director of an administrative department has the initial responsibility to review the disclosure form to determine whether it is (1) a negative disclosure, revealing no conflict or (2) a positive disclosure requiring additional review. If the department chair or director of the administrative unit determines that the activities disclosed do not present a conflict of interest, he/she will record the decision on the disclosure form and forward it to the dean of the appropriate school or college or vice chancellor for the administrative department for his/her review and approval. If the activity is determined not to be in conflict with university obligations, the form will be filed in the Covered Employee's personnel file. Copies of the disclosure forms will be maintained in confidence by the department chair or director of the administrative unit.
- 6.2.5 The department chair or director may conclude that (a) a conflict exists, but the nature and degree of the conflict are not significant and do not warrant disclosure beyond the initial disclosure and documentation; (b) a conflict exists that may be mitigated though a management plan; or (c) a conflict of interest exists and the activities are not allowable under any circumstances. The department chair or director will confer with the dean or vice chancellor in making a final determination of conflict of interest. These individuals may seek advice and counsel from the Conflict of Interest Committee in making a final determination. If the department chair or director and the dean or vice chancellor determine that a conflict of interest exists that may be mitigated through a management plan, they will work with the Covered Employee to develop a conflict of interest management plan. They may seek advice and assistance from the Conflict of Interest Committee in the development of the management plan. The dean or vice chancellor and the Conflict of Interest Committee must approve the management plan prior to the employee's engagement in the disclosed activities.
- 6.2.6 Management plans may include, but are not limited to, requiring public disclosure of financial interests; requiring that the research or other activity be monitored by neutral, independent reviewers; requiring modification of the research plan or work plan; requiring that a Covered Employee with a conflicting interest be disqualified from participation in a particular project or activity or specified parts of the project or activity; or requiring divestiture or

severance of significant financial or other interests which create conflict with the EHRA employee's university employment responsibilities.

- 6.2.7 Management plans must include the name of the Covered Employee who has the conflict of interest, the name of the entity with the which the EHRA employee has an interest that may conflict with university interest, the nature of the conflict of interest, and the value of the financial interest. The key elements of the management plan include the conditions of the management plan, confirmation of the Covered Employee's agreement to the management plan, and how the management plan will be monitored to ensure compliance by the Covered Employee. Department chairs or directors are responsible for monitoring a Covered Employee's compliance with the management plan.
- 6.2.8 The Conflict of Interest (COI) Committee is recommended by the Provost and VC for academic affairs. This committee is responsible for providing counsel and assistance to department chairs, directors, deans and vice chancellors in the determination of a conflict of interest at their request. The committee will review conflict of interest disclosures referred to them by the chairs, directors, deans, or vice chancellors and approve proposed management plans regarding conflict of interest management, mitigation, or elimination. It will assist with investigations and reporting obligations concerning undisclosed conflicts of interest and violations of this policy and federal law and regulations. The Conflict of Interest Committee will consist of three (3) members appointed by the chancellor, at least one (1) of whom shall be chosen from non-faculty personnel, and four (4) faculty members from a pool jointly recommended by the chair of the Faculty Senate and the provost and VC for academic affairs. Members will be appointed for three (3) year staggered terms, one (1) of whom shall be designated by the chancellor to serve as the chairperson.
- 6.2.9 A Covered Employee has the right to appeal a determination that a conflict of interest exists and/or the terms and conditions of the recommended management plan. The Covered Employee must prepare a short, written statement that describes the nature of the appeal and the remedy sought. The appeal must be submitted to the chancellor within ten (10) business days of the receipt of the decision of the Conflict of Interest Committee. The decision of the chancellor is final.
- 6.2.10 Requirement of Disclosure of Potential Conflicts of Interest for Research Projects. The following sections describe the procedures for disclosure, review, and monitoring of potential conflicts of interest for both non-PHS-funded and PHS-funded researchers. The overall process for disclosure, review, and monitoring is the same for both categories of research. Both categories require timely disclosure by all researchers who are responsible for the design, conduct, and reporting of the research. Both categories will be reviewed and monitored by the Conflict of Interest Committee (COI), with the ultimate determination and authority over FCOIs residing with the provost and VC of Academic Affairs (FCOI Institutional Official).
- 6.2.10.1 Disclosure of Potential Conflicts of Interest for Non-PHS-Funded Research All Covered Employees

- 6.2.10.1.1 All investigators, including the principal investigator, co-principal investigator, and any other individual responsible for the design, conduct, or reporting of the proposed or funded research activities must disclose any conflict of interest that would reasonably appear to be related to and potentially affect the proposed or funded research activities.
- 6.2.10.1.2 The disclosure of potential conflicts of interest is made by the investigator at the time of proposal submission. If a financial interest is disclosed by the investigator, the investigator must also complete a Financial Interests Affecting Research (FIAR) form which must also be signed by the chair and dean. On the FIAR form, the employee must disclose all financial interests (excepting the excluded categories provided in section 3.12) held by the employee, his/her spouse, and/or children over the previous twelve (12) month period that could affect the proposed research, along with the dollar value of the financial interest(s).
- 6.2.10.1.3 These disclosure requirements also apply to university investigators whose research is funded by internal university funds. Such investigators are responsible for promptly disclosing any financial conflicts of interest via the FIAR form to their chair and dean before starting the research project, who shall then forward the disclosure to the COI Committee.
- 6.2.10.2 Institutional Review and Monitoring of Potential Conflicts of Interests for Non-PHS-Funded Research All Covered Employees
- 6.2.10.2.1 If a potential conflict of interest is disclosed by an investigator, his/her dean will immediately route the FIAR to the chair of the COI Committee and to the Office of Sponsored Research and Programs (OSRP). The COI Committee will review each disclosure to determine whether it is (1) a disclosure revealing no conflict, or (2) a disclosure requiring additional review. Although the National Science Foundation defines Significant Financial Interests at the minimum financial threshold of \$10,000 or greater in the aggregate over the preceding twelve (12) months, UNC Pembroke COI Committee members will use their reason and judgment to assess potential conflicts of interest regardless of the monetary level.
- 6.2.10.2.1.2 If it appears that a potential conflict of interest exists, the COI Committee, in consultation with the investigator, the chair, and the dean, will develop and recommend an appropriate management plan. Actions may include the having the employee take the necessary steps to eliminate the conflict of interest, a determination that the potential conflict of interest is actually permissible, or that other action needs to be taken.
- 6.2.10.2.1.3 The FIAR form, along with the COI Committee's decision and recommendation, will be forwarded to the provost and VC for academic affairs for final review and approval. The final review and approval will be communicated in writing to all parties (investigator, chair, dean, OSRP). If the activity is determined not to be in conflict with university obligations, the FIAR form will be filed in the Covered Employee's personnel file maintained in the Office of Academic Affairs. If an FCOI is found to exist, the COI Committee, along with the chair and dean, will be responsible for ongoing monitoring of the management plan, with regular reports provided to the provost and VC for academic affairs.

- 6.2.10.2.1.4 If the Covered Employee and/or their chair (or department head) does not agree with the COI Committee's recommendation or provost's and VC for academic affairs' decision regarding the potential for conflict of interest and/or actions to be taken, s/he can appeal the recommendation and/or decision through the chancellor.
- 6.2.10.2.1.5 UNC Pembroke will not execute funding award documents or allow expenditures of funded research if the Covered Employee's FIAR forms are not completed or if the COI Committee's review and resolution of any conflict is not yet completed and approved. Conflicts which cannot be satisfactorily managed, reduced, or eliminated will be disclosed to the sponsoring federal agency, as applicable.
- 6.2.10.3 Disclosure of Financial Interests/Conflicts of Interest PHS-Funded Research
- 6.2.10.3.1 The disclosure, review, and monitoring of PHS-funded research will follow the same general process as outlined above for non-PHS-funded research. For each new or updated disclosure, the investigator will submit a FIAR form to his/her chair and dean for their review and signature, who will forward the disclosure to the committee and to the OSRP. Final committee recommendations will be forwarded to the provost and VC for academic affairs for final institutional review and approval.
- 6.2.10.3.2 Although the overall process is the same, there are several key differences. Significant financial interests for PHS-funded investigators are those that reasonably appear to be related to the investigator's "institutional responsibilities." As a result, PHS-funded researchers must disclose a wider array of financial interests than non-PHS-funded researchers. In addition, they must disclose on a more frequent basis. PHS-funded investigators (including potential collaborators, consultants, and sub-awardee recipients) must disclose all SFIs by means of the FIAR form at the following times and events: 1) at the time of application for PHS-funded research; 2) at least annually during the period of the award; and 3) within thirty (30) days of discovering or acquiring a new SFI (such as travel or consulting). In addition, they must disclose all reimbursed or sponsored travel, regardless of amount, with exclusions, related to their institutional responsibilities; this disclosure must be made within thirty (30) days of the travel. The required information to be disclosed regarding the travel includes the name of the sponsor, purpose of the trip, length of the trip, and destination. Each PHS-funded investigator must also report all paid authorships.
- 6.2.10.3.3 As with non-PHS-funded researchers, PHS-funded researchers are not required to disclose interests excluded per section 3.12.2.5 (e.g., payments for seminars, lectures, teaching engagements, service on advisory committees, review panels of federal, state or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.)
- 6.2.10.4 Institutional Review and Monitoring PHS-Funded Research
- 6.2.10.4.1 For PHS-funded researchers, the university will use the same process for institutional review and approval as described above for non-PHS-funded investigators. As each new interest is disclosed, the investigator must submit a new FIAR to his/her chair and dean. The dean will

route and FIAR forms to the chair of the Conflict of Interest Committee and to the OSRP. The committee will review financial interests both at the time of initial grant application and immediately upon the disclosure of each new financial interest to determine if a significant financial interest (SFI) exists.

6.2.10.4.2 The committee will review each of the investigator's disclosed SFIs relating to his/her institutional responsibilities, and determine: 1) if the SFI relates to or could be affected by the PHS-funded research, and 2) if the SFI could directly and significantly affect the design, conduct, or reporting of the PHS research. If both of these conditions are found to exist, the SFI represents an FCOI. Criteria for relatedness could include: IP, licenses, royalties, products and services provided by the investigator's company, the investigator's relationship with subrecipients, and the investigator's equity relationship to funded research. If an FCOI is found, the committee, with participation by the investigator, chair, and dean, will develop and recommend an appropriate management plan for the FCOI. The committee will forward the disclosure and its findings and recommendations, including the recommended management plan, if any, to the provost and VC for academic affairs for final review and approval. Approval by the provost and VC for academic affairs will be disseminated to all parties (investigator, chair, dean, OSRP). If the activity is determined not to be in conflict with university obligations, the FIAR form will be filed in the Covered Employee's personnel file. If an FCOI is found to exist, the committee, along with the chair and dean, will be responsible for ongoing monitoring of the management plan, with regular reports to the provost and VC for academic affairs.

6.2.10.4.3 This review must be completed prior to the expenditure of funds. If an investigator fails to make timely disclosure of a financial interest, the provost and VC for academic affairs is responsible for ensuring that a management plan is implemented within sixty (60) days.

6.3 Enforcement and Sanctions

6.3.1 Each Covered person is responsible for complying with this policy and all applicable federal law and regulations pertaining to conflicts of interests. Each Covered Employee shall ensure that a conflict of interest or commitment does not occur or is managed appropriately. The appropriate funding agency will be notified in the event that a Covered Employee has a conflict of interest that involves a project funded by that agency. The provost and VC for Academic Affairs is responsible for overseeing the implementation of this policy. The provost and VC for academic affairs will review all reports of breaches of this policy and may refer such reports to the Conflict of Interest Committee for review and recommendations. The university may take appropriate disciplinary action, in accordance with university policies, when a Covered person does not report or resolve an identified conflict of interest, comply with the conflict of interest evaluation process, or comply with a prescribed management plan. Possible sanctions for violation of this policy may include, but are not limited to, administrative actions such as revocation of certain rights and privileges of employment, reprimand, or termination of employment, in accordance with university policies.

6.3.2 PHS-Funded Research

- 6.3.2.1 UNC Pembroke will monitor and enforce full compliance with the FCOI regulations for PHS-funded investigators. The Conflict of Interest Committee will perform ongoing, regular reviews of each management plan, at a time determined for each plan, but at least annually. These reviews shall be submitted to the provost and VC for academic affairs for his/her review and approval.
- 6.3.2.2 If the university determines that an FCOI has not been disclosed or managed in a timely manner, it will complete and document a retrospective review within one-hundred and twenty (120) days following the procedure outlined in section 6.2.10.4. For all PHS-funded clinical research wherein an investigator's FCOI is not managed or reported as required, the investigator will be required to disclose the FCOI in each public presentation of the research and request an addendum to previously published presentations.
- 6.4 Maintenance of Records PHS-Funded Research
- 6.4.1 The Office of Academic Affairs will maintain all FCOI-related records for PHS-funded research for at least three (3) years from the date the final expenditures report is submitted to the PHS.
- 6.5 Sub-recipient Requirements
- 6.5.1 For non-PHS-funded research, UNC Pembroke will take reasonable steps to ensure that investigators working with sub-recipients comply with this policy.
- 6.5.2 For PHS-funded research, UNC Pembroke shall incorporate language as part of each sub-recipient agreement that: 1) establishes whether the university's FCOI policy or that of the sub-recipient will apply to the sub-recipient's investigators; 2) provides for required certification from the sub-recipient that its FCOI policy complies with UNC Pembroke's policy; 3) requires the sub-recipient to report identified FCOIs in a time frame that allows UNC Pembroke to fulfill its reporting requirements to the PHS funding agency; and 4) requires the sub-recipient to solicit and review its investigators' disclosures to enable UNC Pembroke to identify, manage, and report FCOIs to PHS on a timely basis. The principal investigator, working with the OSRP, will be responsible for ensuring that each sub-award agreement incorporates the appropriate terms and conditions. Each sub-recipient is responsible for disclosing initial and new potential conflicts of interest on a timely basis. The university's COI Committee will be responsible for reviewing and assessing identified potential conflicts of interest, and for monitoring any management plans that are required.
- 6.6 Reporting Requirements to PHS PHS-Funded Research
- 6.6.1 The PI, working in collaboration with OSRP, will submit initial, annual, and revised FCOI reports, including management plans, to the applicable PHS agency as required and in accordance with agency guidelines: 1) prior to the expenditure of funds; 2) within sixty (60) days of identification of a new faculty investigator; 3) within sixty (60) days for newly identified FCOIs for existing investigators; 4) at least annually at the same time as the annual progress or other required reports; and 5) following a retrospective review.

- 6.6.2 For each annual report, the university will provide the funding agency the details of each FCOI, including: name of the individual having the FCOI; name of the entity in which the investigator has the financial interest; nature and magnitude of the interest within ranges (e.g., <\$5K, <\$10K, <\$20K, etc.), as the basis of the FCOI determination; and the key elements of the management plan. The committee and the OSRP will provide annual updates for the duration of the research project.
- 6.6.3 The university will promptly notify the PHS agency if: 1) bias is found with the design, conduct, or reporting of PHS-funded research; 2) an investigator fails to comply with UNC Pembroke's FCOI policy; or 3) a management plan appears to have biased the research. In such case, the university will promptly submit a mitigation report, and take corrective action as required in accordance with the procedures described in sections 6.2.10.4 and 6.3.2.2.
- 6.7 PHS-Funded Research Training Requirements
- 6.7.1 Conflict of interest training is mandatory for all UNC Pembroke PHS-funded investigators who are responsible for the design, conduct, or reporting of research. This training requirement applies to all UNC Pembroke investigators, along with any external investigators such as collaborators, consultants, and sub-award recipients, who share responsibility for the design, conduct, or reporting of the research. Each person so identified must complete the university's FCOI training prior to engaging in such research and every four (4) years thereafter. Training must immediately be completed if an investigator is found to be out of compliance with the policy or out of compliance with a management plan developed to mitigate an identified FCOI. The Office of Sponsored Research and Programs (OSRP) is responsible for providing and monitoring the conflict of interest training for prospective PHS-funded investigators and sub-recipients. Sub-award investigators and contractors must be named at the time of application and must complete the necessary disclosures and training.
- 6.8 Public Accessibility Requirements
- 6.8.1 UNC Pembroke will ensure accessibility to the public of its FCOI policy and determinations. The university will make its FCOI policy available on its UNC Pembroke publicly accessible website.
- 6.8.2 PHS-Funded Research. For senior/key personnel, certain details of each FCOI will be made available to the public upon request. The information to be provided will include: name, research role, entity, nature of SFI, and dollar range. This information shall be provided by the Office of General Counsel.
- 6.9 Disclosure and Institutional Review and Approval of External Professional Activities for Pay
- 6.9.1 UNC Pembroke adheres to <u>UNC Policy Manual 300.2.2.1[R]</u> "Regulations on External Professional Activities for Pay by Faculty and Non-Faculty EHRA Employees."

- 6.10 Dissemination of the Policy on Conflict of Interest and Conflicts of Commitment and Training of Covered Employees.
- 6.10.1 This policy is disseminated to all university faculty members and non-faculty employees to ensure that they are aware of university requirements and employee responsibilities. The policy is posted to the university's Policies and Regulations website where it can be accessed by all Covered Employees and the entire campus. Also, all Covered Employees are fully informed about the requirements of the university policy on conflicts of interest and conflicts of commitment through training on a regular and continuing basis. It is the responsibility of every department chair and director to ensure that his/her Covered Employees receive training. Department chairs and directors should consult with the Office of Human Resources on the provision of this training for Covered Employees.