

Conflict of Interest and Commitment

Policy 604.6

1 Introduction

1.1 The Code of The University of North Carolina affirms that the basic mission of the faculty is "the transmission and advancement of knowledge and understanding". Faculty employment at Appalachian State University ("University") entails the core responsibilities of teaching, scholarly research and publication, and other professional service to the institution and to society. Faculty and non-faculty EHRA employees (Covered Employees, as more fully defined below) pursue their specialized professional interests in other contexts, collateral to their immediate University employment. These activities demonstrate active participation in a profession and are encouraged, provided they do not conflict or interfere with the timely and effective performance of the individual's primary university duties or University policies.

1.2 As relationships between Covered Employees and private industry, federal and state governments, and nonprofit agencies have grown in number and scope, there has been a corresponding increase in concern about Conflicts of Interest and Commitment. This Policy provides principles and corresponding procedures to identify, address, and manage actual and potential conflicts that would detract from or interfere with a Covered Employee's dedication of unbiased primary professional loyalty, time and energy to University teaching, scholarship, and service.

1.3 This Policy is also intended to comply with state and federal laws and regulations directed at conflicts of interest and commitment. North Carolina law prohibits state employees from directly or indirectly entering into or otherwise participating in any business transaction involving public funds (regardless of source of funds) with any firm, corporation, partnership, person or association which had a financial association with that employee in the preceding two years. North Carolina law explicitly prohibits self-dealing (using one's University position to gain an unfair personal business advantage), misuse of confidential University information for personal gain, and having any personal interest in supplying any goods to the State. Federal regulations issued by the National Science Foundation and Public Health Service ("PHS") establish requirements for University research funded by those agencies.

1.4. Activities undertaken by University faculty, staff, students, and Covered Individuals (as defined below) in furtherance of the University mission must be conducted in an ethical and transparent manner consistent with federal and state law and University policy. Covered Persons (as defined below) are expected to avoid conflicts of interest and commitment that have the potential to directly and significantly (1) affect the interests of the University; (2) compromise objectivity in carrying out University Employment Responsibilities and PHS responsibilities; or (3) otherwise compromise the performance of University Employment Responsibilities. This Policy requires: an annual or, if needed, more frequent, disclosure of outside interests; and a management process which supplements other University policies such as the External Professional Activities of Faculty and Other Professional Staff policy.

2 Scope

2.1 Each Covered Employee and Covered Individual, as these terms are defined below, is required to comply with this policy.

3 Definitions

3.1 Conflict of Interest ("COI")

relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, involve the potential for compromising, or have the appearance of compromising a Covered Employee's objectivity in fulfilling the Covered Employee's University duties or responsibilities, including research, service and teaching activities and administrative duties.

3.2 COI Coordinator

is the University's Provost or the Provost's designee.

3.3 Conflict of Commitment

relates to a Covered Employee's distribution of time and effort between obligations to University employment and participation in other activities outside of University employment. A conflict of commitment occurs when the pursuit of such outside activities involves an investment of time or is conducted at a time that interferes with the employee's fulfillment of

University Employment Responsibilities.

3.4 Covered Employee (also referred to as “Covered Person”)

is defined as any faculty or EHRA non-faculty employee of the University of North Carolina or a Constituent Institution, an affiliated entity, or other agency or unit of the University of North Carolina.

3.5 Covered Individual (also referred to as “Covered Person”)

includes any person who is a Principal Investigator or Project Director of any Public Health Service-supported grant received by the University, and any person who is designated by a Principal Investigator or Project Director of any Public Health Service-supported grant as being responsible for the design, conduct, or reporting of the Public Health Service-funded research, or who is listed as Senior/Key Personnel on any grant application or report submitted to the Public Health Service. Covered Individuals may include any subcontractor, collaborator, student, or consultant who is responsible for any portion of the design, conduct, or reporting of Public Health Service-funded research performed under a grant to the University, regardless of whether that individual is compensated for work or is an employee of the University.

3.6 Department

means an academic department or any other administrative unit designated by the Chancellor for the purposes of implementing this policy.

3.7 Designated University Official (“DUO”)

means the Dean of the Covered Person’s college or, for any Covered Person not assigned to a position in any college, the appropriate unit head.

3.8 Disclosure Form

means the Conflict of Interest and Commitment Disclosure Form and any addenda thereto required to be submitted by a Covered Person in accordance with this policy. Submission of Disclosure Forms may be made in electronic format.

3.9 External Professional Activities for Pay

are any Covered Employee activities that:

- 1) are not included within one's University Employment Responsibilities;
- 2) are performed for any entity, public or private, other than the University employer;
- 3) are undertaken for compensation; and
- 4) are based upon the professional knowledge, experience and abilities of the Covered Employee.

3.10 Executive Position

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

3.11 Financial Interest

is defined as:

1. Payment for services to the Covered Person not including institutional salary of Covered Employees;
2. Equity or other ownership in a publicly or non-publicly traded entity (e.g., stock, stock options, or other ownership interest);
or
3. Intellectual property rights and interests in receipt of income related to such rights, and interest, held by the Covered Person or members of the Covered Person’s Immediate Family.

Income from investment vehicles, such as mutual funds or retirement accounts, in which the Covered Person or Immediate Family member do not directly control the investment decisions; 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.

3.12 Immediate Family of a Covered Person

includes the Covered Person’s spouse and dependent children.

3.13 Public Health Service (PHS)

means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

3.14 PHS Responsibilities

refer to a Covered Individual's responsibilities for a PHS proposal or grant.

3.15 PHS Financial Conflict of Interest (also referred to as "PHS FCOI")

means any PHS Significant Financial Interest that the University determines is related to a PHS-funded research project and could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

3.16 PHS Significant Financial Interest

is defined as follows:

1. A Financial Interest consisting of one or more of the following interests of the Covered Individual (and those of the Covered Individual's Immediate Family) that reasonably appears to be related to the Covered Individual's University Employment Responsibilities or PHS Responsibilities:
 1. With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received by the Covered Individual or Immediate Family from the entity in the twelve months preceding the disclosure and the value of any equity interest held by the Covered Individual or Immediate Family in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 2. With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received by the Covered Individual or Immediate Family from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Covered Individual or Immediate Family holds any equity interest (e.g., stock, stock option, or other ownership interest) in the entity; and
 3. A PHS Significant Financial Interest exists with respect to any intellectual property rights and interests (e.g., patents, copyrights), in receipt of income related to such rights and interests by the Covered Individual or Immediate Family.
2. A PHS Significant Financial Interest also exists upon the occurrence of any reimbursed or sponsored travel (i.e., any travel which is paid on behalf of the Covered Individual and not reimbursed by the Covered Individual regardless of whether the exact monetary value is readily determinable) related to the Covered Individual's University Employment Responsibilities.
3. The term PHS Significant Financial Interest does not include the following types of financial interests:
 1. salary, royalties, or other remuneration paid by the University to the Covered Individual if the Covered Individual 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;
 2. income from investment vehicles, such as mutual funds and retirement accounts, as long as neither the Covered Individual nor any member of the Covered Individual's Immediate Family directly controls the investment decisions made in these vehicles;
 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;
 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 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; or
 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.

3.17 Senior/Key Personnel

means the Project Director or Principal Investigator and any other person identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the PHS by the University.

3.18 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 and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from the University;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. An equity interest that when aggregated for the Covered Person and that individual'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
5. Salary, royalties or other payments, including consulting fees, that when aggregated for the Covered Person and Immediate Family over the next twelve months, are not expected to exceed \$10,000.

3.19 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.

3.20 University

means Appalachian State University, including its primary campus located in Boone, North Carolina, and all locations controlled and operated by it.

3.21 University Employment Responsibilities

include Primary Duties and Secondary Duties. Primary Duties consist of assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties. Secondary Duties may include professional affiliations and activities traditionally undertaken by Covered Employees outside of the immediate University employment context. Secondary Duties may or may not entail the receipt of honoraria, remuneration or the reimbursement of expenses, include membership in and service to professional associations and learned societies; membership on professional review or advisory panels; presentation of lectures, papers, concerts or exhibits; participation in seminars and conferences; reviewing or editing scholarly publications and books without receipt of compensation; and service to accreditation bodies.

4 Policy and Procedure Statements

4.1 Conflicts of Interest

4.1.1 Conflicts of interest refer to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a Covered Person's objectivity in fulfilling University Employment Responsibilities or PHS Responsibilities. Covered Persons may have a conflict of interest when they, or any member of their Immediate Families, have a personal interest in an activity that may affect their decision making with respect to their University Employment Responsibilities or PHS Responsibilities. 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 Person who is in a position to make a supervisory, academic, research, or administrative decision which may be compromised because of potential financial gain from a Financial Interest. The bias that such conflicts may impart can affect many University duties, including decisions about personnel, the purchase of equipment and other supplies, the selection of instructional materials for classroom use, the collection, analysis and interpretation of data, the sharing of research results, the choice of research protocols, the use of statistical methods and the mentoring and judgment of student work.

4.1.2 Activities that may involve Conflicts of Interest fall under four general categories. Each category includes examples that are provided for illustrative purposes, but do not include all possible situations.

4.1.3 Category 1: Allowable activities requiring disclosure. Category 1 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 but are not limited to:

1. A Covered Employee receiving royalties from the publication of books or for the licensure of patented inventions subject to the Appalachian State University and UNC Patent and Copyright Policies.
2. A Covered Employee receiving compensation in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works and participation in accreditation reviews. Covered Employees must comply with the External Professional Activities of Faculty and Other Professional Staff Policy.

4.1.4 Category 2: Activities requiring disclosure for further administrative review and analysis. Category 2 includes activities that 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 include but are not limited to:

1. A Covered Employee requiring students to purchase the textbook or related instructional materials authored or compiled by the employee or members of the employee's Immediate Family, which produces compensation for the employee or family member.
2. A Covered Employee receiving compensation or gratuities from any individual or entity doing business with the University. Under North Carolina state law, 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 the employer.
3. A Covered Person serving on the board of directors or scientific advisory board of an enterprise that provides financial support for University research and the employee or an Immediate Family member may receive such financial support.
4. A Covered Person or an Immediate Family Member having an equity or ownership interest in a publicly or non-publicly-traded entity or enterprise doing business with the University or soliciting business from the University.
5. A Covered Person 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 The UNC Policy Manual, 500.1 and 500.2, and with the University Intellectual Property Transfer policy.

4.1.5 Category 3: Activities or relationships that are generally not allowable or permitted unless an approved Conflict of Interest management plan is in place. Activities in Category 3 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. An approved Conflict of Interest management plan is required for these types of activities. Examples include but are not limited to:

1. A Covered Person participating in University research involving a technology owned by or contractually obligated to (by license or an option to license, or otherwise) the Covered Person 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.
2. A Covered Person 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.
3. A Covered Person 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.

4.1.6 Category 4: Activities that are not allowable under any circumstances. Examples include but are not limited to:

1. A Covered Person making referrals of University business to an external enterprise in which the individual or an Immediate Family member has a financial interest.
2. A Covered Person associating his or her own name with the University in such a way as to profit financially by trading on the reputation or goodwill of the University.
3. A Covered Employee making unauthorized use of privileged information acquired in connection with the Covered Employee's University Employment Responsibilities.
4. A Covered Employee signing agreements that assign University patent and other intellectual property rights to third parties without prior University approval.
5. Any activity otherwise prohibited by law or University policy.

4.2 Conflicts of Commitment

4.2.1 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. The latter may include such generally encouraged extensions of professional expertise as professional consulting (i.e., External Professional Activities for Pay). Such activities promote professional development and enrich the individual's contributions to the institution, to the profession, and to society. However, a conflict of commitment occurs when the pursuit of such outside activities involves an investment of time or is conducted at a time that interferes with the employee's fulfillment of University Employment Responsibilities.

4.2.2. Although full-time faculty and other non-faculty EHRA employment is not amenable to precise, time-clock analysis and monitoring, administrators at the department and other unit levels regularly evaluate the work of employees within their units. The formal occasions for determining whether an individual is devoting sufficient time and effort to University employment include regular reviews of performance in connection with annual salary decisions and scheduled reviews incident to promotion, reappointment or tenure decisions. In addition, complaints from students, colleagues, or administrators about possible failures to meet assigned responsibilities may arise and require investigation. The issue, in each case, is whether the employee is meeting the requirements of the job. Evidence that a Covered Employee is not meeting full-time responsibilities to the University may

result in employment discipline up to and including dismissal.

4.2.3 The University policy on External Professional Activities of Faculty and Other Professional Staff requires that a University employee who wishes to engage in an External Professional Activity for Pay must make a full disclosure, in advance, of the planned outside involvement and must provide satisfactory assurances that such activity will not interfere with University employment obligations by completing the "Notice of Intent to Engage In External Professional Activity for Pay". A person engaged in External Professional Activities for Pay may not use University Resources in the course and conduct of externally compensated activities. Under no circumstances may any employee use the services of another employee during University employment time to advance the externally compensated employee's professional activities for pay.

4.2.4 In those instances when State-reimbursed travel, work time, or resources are used or when the activity can be construed as related to the Covered Employee's University Employment Responsibilities on behalf of the State, the employee shall not receive any financial consideration, including an honorarium. In these instances the employee may request that the honorarium be paid to the University. The honorarium may be retained by the employee only for activities performed outside of normal working hours, as defined by the institution, or while the employee is on earned paid or annual leave, and all expenses are the responsibility of the employee or a third party that is not a State entity. Senior Academic and Administrative Officers are subject to further restrictions on the receipt of an honorarium and requirements that annual leave been taken pursuant to the UNC Policy Manual, 300.2.2.2[R].

4.3 Public Health Service Rules, Requirements and Responsibilities

4.3.1 The Public Health Service (PHS) and the U.S. Department of Health and Human Services issued revised regulations on the "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors" (commonly known as the Financial Conflict of Interest (FCOI) regulations) on August 25, 2011. These regulations, available at <http://grants.nih.gov/grants/policy/coi>, establish new standards and clarify previously issued standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The primary goal of the new regulations is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and research contracts will be free from bias resulting from Investigator financial conflicts of interest.

4.3.2 Covered Individuals' Responsibilities Under the PHS FCOI Regulation. Covered Individuals have the following responsibilities regarding disclosure of PHS Significant Financial Interests:

4.3.2.1 Disclosures of PHS Significant Financial Interests for Covered Individuals Applying for or Participating in PHS-Funded Research. In addition to the annual disclosures required under this policy, any Covered Individual applying for PHS-funded research grants must update his or her Disclosure Form to disclose to the COI Coordinator or update as needed all PHS Significant Financial Interests at the time of application for the PHS-funded research grant. Each Covered Individual participating in PHS-funded research must also update the Covered Individual's Disclosure Form within 30 days of discovering or acquiring (for example, through inheritance or marriage or participating in sponsored or reimbursed travel) a new PHS Significant Financial Interest.

4.3.2.2 Training. All Covered Individuals applying for PHS-funded research grants or participating in PHS-funded research are required to complete training provided by the COI Coordinator in PHS regulations to promote objectivity in research prior to participating in research related to any PHS-funded grant and at least every four years thereafter for so long as they continue to apply for PHS-funded grants or participate in PHS-funded research. In addition, Covered Individuals must also complete such training whenever (a) the University revises this policy in a manner that affects the Covered Individuals; (b) the Covered Individual is new to the University; or (c) the University finds that the Covered Individual is not in compliance with this policy or any management plan developed under this policy.

4.3.2.3 Disclosure of Sponsored or Reimbursed Travel. Covered Individuals must disclose to the COI Coordinator reimbursed or sponsored travel and report at a minimum the following information:

1. The purpose of the trip;
2. The identity of the sponsor and/or organizer of the trip;
3. The destination; and
4. The duration of the trip

The COI Coordinator or DUO may require disclosure of additional information such as the monetary value of any such travel.

4.3.3 Institutional Responsibilities under the PHS FCOI Regulation

4.3.3.1 Sub-recipients of PHS-Funded Research Grants. If the University carries out PHS-funded research through a sub-recipient such as a subcontractor or a consortium, the Chief Research Officer (CRO) will ensure via written agreement that the sub-recipient either follows this policy or a financial conflict of interest policy of the sub-recipient's employer. If the sub-recipient complies with its own employer's financial conflict of interest policy, the University and the sub-recipient must, prior to sub-

recipient's performance of any PHS-funded work, enter into a written agreement (a) certifying that the sub-recipient's conflict of interest policy complies with the PHS regulations for promoting objectivity in research as codified at Title 42 of the Code of Federal Regulations, Part 50, Subpart F and (b) specifying that the sub-recipient will report all PHS Financial Conflicts of Interest identified under its policy to the University prior to full execution of the written agreement and within 30 days following discovery or acquisition of a new PHS Significant Financial Interest in a manner sufficient to allow the University to provide complete and timely reports to the PHS. Alternatively, the University and the sub-recipient may enter into a written agreement (a) acknowledging that the sub-recipient's employees who are responsible for the design, conduct, or reporting of the PHS-funded research are subject to this policy and (b) specifying that the sub-recipient will submit disclosures of PHS Significant Financial Interests from the sub-recipient's employees who are responsible for the design, conduct, or reporting of the PHS-funded research to the University at the point of application to PHS and within 30 days following discovery or acquisition of any new PHS Significant Financial Interest in a manner sufficient to allow the University to comply with its review, management, and reporting obligations to the PHS.

4.3.3.2 Review of PHS Significant Financial Interests. In reviewing a Covered Individual's PHS Significant Financial Interests, the COI Coordinator will first determine whether any PHS Significant Financial Interest is related to the Covered Individual's PHS-funded research. The PHS Significant Financial Interest is related to a PHS-funded research project if the PHS Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the PHS-funded research. If the PHS Significant Financial Interest is determined to be related to PHS-funded research, then the COI Coordinator consults with the Designated University Official (DUO) to determine whether the PHS Significant Financial Interest constitutes a PHS Financial Conflict of Interest and, if so, follows the procedures described in this policy to develop, document, and recommend an appropriate management plan to a DUO. The DUO monitors the Covered Individual's compliance with the management plan on an ongoing basis until completion of the PHS-funded project. For any new PHS-funded project, the review of all relevant disclosures of Financial Interests and implementation of any management plans must be complete prior to expenditure of any funds for the project. For a Covered Individual who is new to the PHS-funded project or any Covered Individual who discloses a new PHS Significant Financial Interest after the start of the project, review of the disclosure of PHS Significant Financial Interests and implementation of the management plan, if any, must be complete within 60 days of disclosure.

4.3.3.3 Reporting of PHS Financial Conflicts of Interest to the PHS. For any PHS Financial Conflict of Interest identified and not eliminated, the DUO will provide the Office of Sponsored Programs with a report including sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the University's management plan, including all documentation of any management plan. The Office of Sponsored Programs will file the initial report with PHS prior to any expenditure of funds. After the initial report has been submitted, the Office of Sponsored Programs will submit to the PHS reports for each PHS Financial Conflict of Interest for the duration of each project (including funded or unfunded extensions) at the same time as the University submits the annual progress report, multi-year progress report (if applicable), or at the time of extension. The annual reports 1) must address the status of each relevant PHS Financial Conflict of Interest, and any changes to the management plan and 2) must specify whether the PHS Financial Conflict of Interest is still being managed or explain why the PHS Financial Conflict of Interest no longer exists. If a Covered Individual who is newly participating in a project is identified as having a PHS Financial Conflict of Interest, or if any Covered Individual participating in a PHS-funded project discloses a new PHS Significant Financial Interest that is determined to be a PHS Financial Conflict of Interest after the start of the project, a report of that PHS Financial Conflict of Interest, including documentation of its associated management plan, must be sent to the PHS awarding component within 60 days after the PHS Financial Conflict of Interest has been identified.

4.3.3.4 Disclosure of PHS Financial Conflicts of Interest to the Public. Prior to the expenditure of PHS funds, the University must ensure public accessibility and respond to requests for information concerning PHS Financial Conflicts of Interest associated with projects that are currently headed by Covered Individuals. The COI Coordinator will respond in writing within five (5) business days following receipt of a request. The information in the response must be updated at least annually, must be maintained for a period of three years from the last update, and must include the following data elements:

1. Name of the Covered Individual;
2. Title of the Covered Individual;
3. Role of the Covered Individual with respect to the relevant research project;
4. Name of the entity in which the significant financial interest is held;
5. Nature of the PHS Financial Conflict of Interest; and
6. Approximate dollar value of the PHS Significant Financial Interest (the following dollar ranges are permissible: \$0 to \$4,999; \$5,000 to \$9,999; \$10,000 to \$19,999; \$20,000 to \$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000), or a statement if the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

4.3.3.5 PHS Financial Conflicts of Interest that were Not Timely Identified or Managed or For Which a Covered Individual Fails to Comply with a Management Plan. If the University identifies a PHS Significant Financial Interest that was not timely disclosed by a Covered Individual or was not previously reviewed by the University during an ongoing PHS-funded research project (such as, for instance, a PHS Significant Financial Interest that was not timely reviewed or reported by a sub-recipient), the COI Coordinator must, within 60 days of such identification, determine whether a PHS Financial Conflict of Interest exists and, if so,

recommend to the DUO a management plan that specifies the actions that have been and will be taken to manage the PHS Financial Conflict of Interest. In all such cases and in situations in which a Covered Individual has failed to comply with a management plan, the DUO must, within 120 days of the University's determination of non-compliance, complete a retrospective review of the Covered Individual's activities and the PHS-funded project to determine whether the PHS-funded research, or any portion thereof, conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research and document the retrospective review. The documentation must include at a minimum:

1. The project number;
2. The project title;
3. The Project Director or Principal Investigator (or contact Project Director or contact Principal Investigator if a multiple Project Director/Principal Investigator model is used);
4. The name of the Covered Individual with the PHS Financial Conflict of Interest;
5. The name of the entity with which the Covered Individual has a PHS Financial Conflict of Interest;
6. The reason(s) for the retrospective review;
7. The detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the DUO will inform the Office of Sponsored Programs, which will update the previously submitted PHS Financial Conflict of Interest report, specifying actions that will be taken to manage the PHS Financial Conflict of Interest going forward. If bias is found, the Office of Sponsored Programs must notify the PHS awarding component and submit a mitigation report to the PHS awarding component. The mitigation report must include at a minimum:

1. The key elements documented in the retrospective review;
2. A description of the impact of the bias on the research project;
3. The University's plan of action(s) to be taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project); and
4. The extent of harm done, including any qualitative or quantitative data to support any actual or future harm and analysis of whether the research project is salvageable.

4.3.3.6 Special Remedies for Specific PHS-funded Research Projects. If the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Individual with a PHS Financial Conflict of Interest that was not managed or reported by the University as required by PHS regulations, the DUO must require the Covered Individual to disclose the PHS Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

4.4 Policy Distribution

4.4.1 This policy will be published in the University Policy Manual that is available on the website policy.appstate.edu. Covered Employees are informed of the Policy and their responsibilities at the following times: annually, upon hire, when policy revisions affect the requirements of Covered Employees, when the Covered Employee applies for external funding, and when a Covered Employee is found not in compliance with this policy or a Conflict of Interest management plan.

4.4.2 Covered Individuals who are not Covered Employees are informed of this policy and their responsibilities by the Office of Sponsored Programs when a Principal Investigator/Project Director of any PHS proposal or grant identifies Senior/Key Personnel who are not Covered Employees.

4.4.3 Forms will be made available by the COI Coordinator each year, and by the Office of Sponsored Programs whenever an employee applies for external funding.

4.5 Policy Implementation

4.5.1 The Provost is responsible for overseeing the implementation of this policy in all units, including the process and mechanism for conflict disclosure, evaluation, and management. The Provost has designated the Vice Provost for Research as the Conflicts of Interest (COI) Coordinator. The COI Coordinator will solicit, review and evaluate disclosures of financial interests from Covered Persons, and advise DUOs on development and implementation of plans to manage Conflicts of Interest.

4.5.2 The Chancellor will appoint a standing Conflicts of Interest and Commitment Council (Council) consisting of three members appointed by the Chancellor, at least one of whom shall be chosen from EHRA non-faculty personnel and four faculty members from a pool jointly recommended by the chair of the Faculty Senate and the CRO. The Chancellor shall appoint the chair of the Council from the membership. The CRO and the Director of Sponsored Programs shall serve as ex-officio (non-voting) members of the Council.

4.5.3 The Council will review policies, management plans and other Conflicts of Interest or Commitment matters upon request of any dean, vice chancellor or the Chancellor and make recommendations to the referring official. Covered Persons directly affected by an existing or proposed management plan will be given notice and the opportunity to respond in person and in writing to the issues raised in the course of such management plan reviews. Any such written response will be appended to the Council's report for review by the referring official.

4.5.4 Covered Persons have the right to appeal determinations of their Conflicts of Interests, requirements of a management plan, and determinations of noncompliance with this policy to the Faculty Grievance Hearing Committee pursuant to section 4.11.3 of the Faculty Handbook or pursuant to the provisions of Policy 602.23 EHRA Non-Faculty Grievances (<http://policy.appstate.edu>).

4.5.5 The Council may promulgate rules of procedure for its operations. When promulgated, these rules shall constitute the exclusive formal procedures for the adjudication of appeals herein described.

4.5.6 The primary device for monitoring compliance with this policy is the Disclosure Form designed to reveal income sources, business relationships and activities that may suggest the existence or appearance of a Conflict of Interest or Conflict of Commitment. Covered Persons must amend or supplement such disclosure forms in a timely manner, but in no event more than 30 days following notice, to reflect new developments after submission of the Disclosure Form.

4.5.7 The COI Coordinator will carefully document and maintain sufficient records of all transactions associated with this policy.

4.6 Procedures for Submission of Disclosure Form

4.6.1 All Covered Persons, including part-time employees and employees on leave if the leave is funded at least partially from University sources, are required to complete and submit the Disclosure Form to the COI Coordinator annually before October 1 each year on a schedule announced by the Provost. Covered Employees are encouraged to seek assistance from their respective Department Chairs or supervisors, Deans or Directors, or the Office of Academic Affairs with questions or special circumstances.

4.6.2 Updated forms must be submitted to the COI Coordinator under the following circumstances:

1. prior to applying for external funding or participating in externally-funded research or other programs;
2. when assuming new University Employment Responsibilities;
3. when external relationships change and give rise to a potential conflict of interest, eliminate a potential conflict previously disclosed, or result in an affirmative answer to any question previously answered in the negative on the Disclosure Form.

4.6.3 The Office of Sponsored Programs is responsible for informing the COI Coordinator and the Department Chair or supervisor of the need for new or updated Disclosure Forms for Covered Persons submitting proposals for external funding.

4.6.4 The Disclosure Form contains information that may have a direct bearing on the individual's employment. The forms, therefore, will be maintained confidentially in a database with access limited to University employees having a need to know the disclosed information.

4.6.5 Covered Individuals participating in any project funded by the PHS should be aware that, as a condition of such participation, the PHS will have access to the employee's Disclosure Form at any time during the project and for a period of three years after the submission of a final expenditures report for that project to the PHS. Except as otherwise noted in this policy for PHS Significant Financial Interests that are identified as PHS Financial Conflicts of Interest, the information disclosed in the Disclosure Form is available only to individuals duly charged with the responsibility for review and conflict management, and the information may be released only in accordance with and as required or allowed by North Carolina law or lawful court order.

4.7 Review and Approval of Disclosure Form

4.7.1 Each Department Chair or other supervisor of a Covered Employee is responsible for ensuring that the Covered Employee Department Chair or supervisor's unit has submitted a completed Disclosure Form to the COI Coordinator. The Office of Sponsored Programs is responsible for informing the COI Coordinator and the Department Chair or supervisor if updated forms are not provided before a PHS proposal or NSF proposal is submitted.

4.7.2 The COI Coordinator is responsible for the initial review and evaluation of the Disclosure Forms following the provisions of this policy. The COI Coordinator will consult with the Covered Person, and the Covered Person's Department Chair or supervisor, Dean, Vice Chancellor or Chancellor, as appropriate, regarding any potential Conflicts of Interest or Conflicts of Commitment of Covered Persons.

4.7.3 The appropriate Dean or Vice Chancellor, or the Chancellor, may at any time request that the COI Coordinator perform a de novo review of any Disclosure Form and related circumstances. Following the review, the COI Coordinator will provide a written report to the referring official.

4.7.4 A Conflict of Interest exists when the DUO determines that the Covered Person's personal considerations, Financial Interests or commitments could directly and significantly affect the Covered Person's performance of University Employment Responsibilities or PHS Responsibilities.

4.8 Identification and Management of Conflicts of Interest/Commitment

4.8.1 Once a Conflict of Interest is identified, COI Coordinator coordinates with the Covered Person's Department Chair or supervisor to collect all relevant information necessary to make an informed judgment on the matter and shares this information with the Covered Person's DUO for a final determination.

4.8.2 The DUO may conclude:

1. a conflict appears to exist, but the nature and degree of conflict are not significant and do not warrant action beyond the initial disclosure and documentation;
2. a conflict of interest exists that may be mitigated through a management plan; or
3. a conflict of interest exists and the activities are not allowable under any circumstances.

4.8.3 The DUO may refer identified Conflicts of Interest/Commitment that may be allowable to the Conflict of Interest/Commitment Council for recommendations on whether a conflict of interest management plan can mitigate the conflict, and if applicable, the elements required in a conflict of interest management plan.

4.8.4 The DUO, with recommendations from the Conflicts of Interest and Commitment Council if requested and with advice from the University's Office of General Counsel, is responsible for approving and implementing any Conflict of Interest management plan.

4.8.5 Management plans may include, but are not limited to:

1. Requiring public disclosure of financial interests.
2. Requiring that the research or other activity be monitored by neutral, independent reviewers.
3. Requiring modification of the research plan or work plan.
4. Requiring that an individual with a conflicting interest be disqualified from participation in a particular project or activity or specified parts of the project or activity.
5. Requiring divestiture or severance of financial or other interests which create conflict with the individual's University Employment Responsibilities or PHS responsibilities.

4.8.6 Documentation of the management plan must, include at a minimum, the following information:

1. The name of the Covered Person who has the Conflict of Interest;
2. The name of the entity with which the Covered Person has an interest that may conflict with University interests;
3. The nature of the Conflict of Interest (e.g., equity interest, consulting fee, travel reimbursement, honorarium);
4. The value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reasonable measures of fair market value. The value may be reported as falling within one of the following ranges: \$0 to \$4,999; \$5,000 to \$9,999; \$10,000 to \$19,999; \$20,000 to \$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000;
5. A description of the key elements of the management plan including
 1. The conditions of the management plan;
 2. Confirmation of the Covered Person's agreement to the management plan;
 3. How the management plan will be monitored to ensure compliance by the Covered Person; and
 4. Other information as needed.
6. If applicable, the project number(s) of any federally funded projects that the DUO feels are related to the conflict;
7. If applicable, the title of each such project;
8. If applicable, the name(s) of the Principal Investigator(s) or Project Director(s) on any such project(s); and
9. If applicable, the following additional information about the management plan:
 1. A description of how the Financial Interest relates to any federally funded project and the basis of the decision that the Financial Interest conflicts with University interests in the project;
 2. The role and principal duties of the Covered Person in each such project; and
 3. A description of how the management plan is designed to safeguard objectivity in the research project(s).

4.8.7 The COI Coordinator reports all identified Conflict of Interests and associated management plans to the Provost, CRO and Director of Sponsored Programs if the conflict involves a grant or contract. The Director of Research Protections has access to all disclosures and management plans which involve a protocol under review by the Institutional Review Board, Institutional Animal Care and Use Committee, and Institutional Biosafety Council and these may be shared confidentially with the body reviewing protocols.

4.8.8 The Office of Sponsored Programs is responsible for sending initial, annual, and revised Financial Conflicts of Interest reports with all elements required by the regulations to the PHS and its sub-recipients, and external sponsors, if applicable.

4.9 Policy Breaches and Noncompliance

4.9.1 As employees with a primary commitment to the University, it is the responsibility of each Covered Person to ensure that a Conflict of Interest or Commitment (or the reasonable perception thereof) does not occur or is managed appropriately. The appropriate funding agency (or agencies) sponsoring the activity will be notified in the event that any employee has a conflict of interest that involves a project funded by the agency.

4.9.2 The Provost or the Provost's designee will review all reports of breaches of this policy, and may refer such reports to the Conflicts of Interest and Commitment Council for review and recommendations. The University may take appropriate disciplinary or other action in accordance with University policies when a Covered Person does not (a) report or resolve an identified conflict (or appearance thereof); (b) comply with the conflict evaluation process (by refusal to respond, by responding knowingly with incomplete or inaccurate information, or otherwise); (c) remedy conflicts; or (d) comply with a prescribed management plan. Retaliation against any person who reports a violation of this policy or who participates in an investigation of an alleged violation of this policy is prohibited and may be the basis for discipline up to and including dismissal.

4.9.3 If a breach of this policy involves a sponsored program, the CRO will investigate whether the Covered Person's failure to comply with this policy has biased the design, conduct of, or reporting on the program. If bias is found, the CRO will take appropriate action to address the matter within the University and promptly notify the awarding agency of corrective action taken or to be taken.

5 Additional References

[Annual Conflict of Interest and Commitment Disclosure Form](#)

[AGrants Conflict of Interest and Commitment Disclosure Form](#)

[Intellectual Property Transfer Policy](#)

[External Professional Activities of Faculty and Other Professional Staff Policy](#)

6 Authority

[42 CFR Part 50](#)

[N.C.G.S. 14-234; N.C.G.S. Chapter 138A](#)

[The UNC Policy Manual, 300.2.2, 300.2.2 G, and 300.2.2.1R](#)

7 Contact Information

Office of Academic Affairs--828-262-2070

Office of Sponsored Programs--828-262-2130

8 Original Effective Date

August 24, 2012

9 Revision Dates

November 9, 2012

July 1, 2014

May 11, 2016