

PRR #01.25.01S

CONFLICT OF INTEREST AND COMMITMENT
PHS RULE

Authority: Issued by the Vice Chancellor for Research, Innovation and Economic Development. Changes or exceptions are subject to the review and approval of the Vice Chancellor for Research, Innovation and Economic Development.

History: First Issued: August 1, 2012

Related Policies: NCSU REG 01.25.01 - Conflicts of Interest and Conflicts of Commitment
UNC Policy 300.2.2 Amended 06/15/2012

Additional References: Regulatory Framework: 42 CFR 50 and 45 CFR 94
Form: <http://www.ncsu.edu/sparcs/coi>

Contact Information: Associate Vice Chancellor for Research Administration

INTRODUCTION

Consistent with UNC Policy 300.2.2 Amended 06/15/2012 governing Conflict of Interest and Commitment, this rule supplements NC State University Regulation 01.25.01 dated February 18, 2010. This supplement is issued by the Vice Chancellor for Research, Innovation and Economic Development and is applicable only to those faculty, staff and students involved in proposing, conducting, and/or reporting research funded by the Public Health Service. In this supplement, the regulatory framework promulgated by the Public Health Service is codified to reconcile the institution's overarching Conflicts of Interest and Commitment regulations with those of the Public Health Service in compliance with 42 CFR Part 50 Subpart F.

This Rule governing financial conflict of interest applies to all Investigators of the Institution engaged in activities funded in part or in whole from the Public Health Service (directly as a primary recipient or indirectly through a subcontract). The Institutional Official is responsible for ensuring implementation of this Rule and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

DEFINITIONS

Conflict of Interest Committee (COI Committee) means the Institution's committee or individual that advises the Institutional Official on conflict of interest matters. The committee consists of at least the Associate Vice Chancellor for Research Administration and the cognizant Associate Dean for Research or other administrator designated by the Dean within an academic college or the Investigator's supervising director or comparable position if outside of an academic department.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

Institutional official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family

related to the Investigator's institutional responsibilities. For the purposes of this Rule, the Institutional Official is designated as the Vice Chancellor for Research, Innovation and Economic Development.

Institutional 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 Investigators outside of the immediate University employment context. Secondary Duties may or may not entail the receipt of honoraria, remuneration or the reimbursement of expenses, including membership in and service to professional associations and learned societies; membership on professional review or advisory panels; presentation of lectures, papers, concerts or exhibits; participation in seminars and conferences; reviewing or editing scholarly publications and books without receipt of compensation; and service to accreditation bodies. These activities, which demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and effective performance of the individual's Primary Duties or University Policies, Rules and Regulations.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, technical staff regardless of classification, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

CONFLICT OF INTEREST:

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

1. DISCLOSURE OF FINANCIAL INTERESTS

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

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

1.1 Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by September 30, 2012 for the previous year.

1.2 Ad hoc Disclosures

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

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

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

1.3 Travel

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

2. REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator or the COI Committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3. REPORTING TO PHS

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

4. INVESTIGATOR NON-COMPLIANCE

4.1 Disciplinary Action

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

A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Rule, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator as well as the investigator's immediate supervisor and appropriate other administrators.

4.2 Retrospective Review

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

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review,

detailed methodology used for the retrospective review, and findings and conclusions of the review.

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

5. TRAINING

Each Investigator must complete training on this Rule prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Rule is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Rule or with a management plan related to their activities. For purposes of this Rule, all PHS-funded Investigators must complete the on-line PHS-COI training utility made available through the SPARCS website at <http://research.ncsu.edu/sparcs/training/>. Perpetual, self-directed training is offered by Public Health Service agencies and is highly encouraged as a supplement to the required on-line training.

6. RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

7. CONFIDENTIALITY

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

8. PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

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

- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

9. REGULATORY AUTHORITY

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