

Research Integrity Office

Conflicts of Interest Guidance

Questions? Email: COI@uncw.edu

Public Health Service/US Department of Health and Human Services Conflict of Interest Requirements

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

Major changes to the [1995 PHS regulations](#) are outlined below and are **required** for individuals that apply for or receive Public Health Service (PHS) funding by means of a grant, cooperative agreement, or contract:

I. Key Definitions

- a) *Senior/Key Personnel* means the project director/principal investigator (PD/PI) and any other person *identified* as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS by the institution under the regulation.
- b) *Investigator* means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk increases that an unidentified FCOI may comprise the research.
- c) *Institutional responsibilities* are defined by the 2011 revised regulation as an investigator’s professional responsibilities on behalf of the institution, and as defined by the institution in its policy on financial conflict of interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as

Institutional Review Boards or Data and Safety Monitoring Boards. The institution can include other professional responsibilities within the definition, as appropriate.

d) A *Financial Conflict of Interest* exists when the institution, through its designated official(s), reasonably determines that an investigator's significant financial interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research

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

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

1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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

The term *significant financial interest* does not include the following types of financial interests:

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

- education; or
- 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.

II. Disclosure of Financial Interests

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

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

a) Annual Disclosures

All investigators must disclose their significant financial interests to the institution, through the Institutional Official, on an annual basis on a date established by the UNCW Provost's Office.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators must disclose their significant financial interests to the institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the investigator has a significant financial interest, the investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her significant financial interests with the outside entity. The institution will not submit a research proposal unless the investigator(s) have submitted such ad hoc disclosures.

In addition, all investigators must submit to the Institutional Official an ad hoc disclosure of any significant financial interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the significant financial interest.

III. 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.

IV. Clinical Trials

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the investigator has a financial interest related to the clinical trial.

V. 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.

VI. Investigator Non-Compliance

a) Disciplinary Action

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

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

b) Retrospective Review

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

Documentation of the retrospective review shall include the project number, project title, PI, name of investigator with the financial conflict of interest, name of the entity with which the investigator has the financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

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

eliminate or mitigate the effect of the bias.

VII. Training

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

For the purposes of this policy sufficient training is demonstrated by completion of the UNCW approved training accessible through the UNC AIR system.

VIII. Record Retention

Disclosure forms are maintained in the AIR system. Where conflict management plans are required the corresponding disclosure forms and management plan will be forwarded to the appropriate dean or second level supervisor for approval and retention in the employee's permanent personnel file. All documents will be retained for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

IX. 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.

X. Public Accessibility

Prior to the expenditure of funds, the institution will respond to any requestor within five business days of the request, information concerning any significant financial interest that meets the following criteria:

- a) The significant financial interest was disclosed and is still held by the investigator;
- b) A determination has been made that the significant financial interest is related to the PHS-funded research; and
- c) A determination has been made that the significant financial interest is a financial conflict of interest.

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

XI. Regulatory Authority

This policy implements the requirements of [42 CFR 50](#) and [45 CFR 94](#); where there are substantive differences between this policy and the requirements, the requirements shall take

precedence.

XII. Management of Conflicting Interests

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

- a) Public disclosure of significant financial interests;
- b) Monitoring of research by independent reviewers;
- c) Modification of the research plan;
- d) Disqualification from participation in all or a portion of the research;
- e) Divestiture of significant financial interests; or
- f) Severance of relationships that create actual or potential conflicts

XIII. Certification Statement for Applications for External Funding

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

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

If you have any questions, please contact Lee Prete at 910-962-7774 or email COI@uncw.edu.

For additional information, a link to the AIR system, and COI resources, please visit the UNCW COI website: <https://uncw.edu/sparc/integrity/COI.html>.