

Objectivity in Research Under Public Health Service Grants, Cooperative Agreements, or Contracts

Version 2

 Print

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Title	Objectivity in Research Under Public Health Service Grants, Cooperative Agreements, or Contracts
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Contact	Office of Research Compliance Administration, Director 252-328-9473.
Related Policies	<p>UNC Policy Manual 300.2.2-Conflicts of Interest and Commitment (https://www.northcarolina.edu/apps/policy/doc.php?id=90)</p> <p>UNC Policy Manual 300.2.2[G]-Guidelines on Implementing the UNC Conflict of Interest and Commitment Policy (https://www.northcarolina.edu/apps/policy/doc.php?id=90%5BG%5D)</p> <p>UNC Policy Manual 300.2.2.1[R]-Regulations on External Professional Activities for Pay by Faculty and Non-faculty EPA Employees (https://www.northcarolina.edu/apps/policy/doc.php?id=90.1%5BR%5D)</p> <p>UNC Policy Manual 300.2.2.2[R]-Regulations for Senior Academic and Administrative Officers on External Professional Activities for Pay and Honoraria (https://www.northcarolina.edu/apps/policy/doc.php?id=90.2%5BR%5D)</p> <p>ECU Faculty Manual Part VIII-Section II (https://www.ecu.edu/cs-acad/fsonline/customcf/currentfacultymanual/part8section2.pdf)</p>
Additional References	<p>Public Health Service Conflict of Interest Regulation, Promoting Objectivity in Science 42 CFR 50 Subpart F (https://www.ecfr.gov/current/title-42/part-50/subpart-F)</p> <p>Public Health Service Regulation on Responsible Prospective Contractors 45 CFR 94 (https://www.ecfr.gov/current/title-45/part-94)</p> <p>NIH Conflicts of Interest Resource Page (https://grants.nih.gov/grants/policy/coi/)</p>

1. Introduction.

1.1. Consistent with, and in supplement to, UNC Policy 300.2.2 Conflicts of Interest and Commitment,

300.2.2[G] Guidelines on Implementing the UNC Conflict of Interest and Commitment Policy, and ECU Faculty Manual Part VIII-Section II Conflicts of Interest and Commitment and External Activities of Faculty and Other Professional Staff, this Regulation implements the Public Health Service's regulations on Financial Conflicts of Interest, including that entitled, "Promoting Objectivity in Research" located at 42 CFR 50 and that entitled, "Responsible Prospective Contractors" located at 45 CFR 94.

1.2. Applicability and Designation of Institutional Official. This Regulation applies to all East Carolina University Investigators engaged in activities funded or proposed to be funded, in whole or in part, from the Public Health Service of the U.S. Department of Health and Human Services (whether directly as a primary recipient or indirectly through a subaward/subcontract) and to each grant, cooperative agreement, and contract with an issue date of the Notice of Award that is on or subsequent to the first issue date of this Regulation. The Vice Chancellor for Research and Graduate Studies is the Institutional Official and is responsible for ensuring implementation of this Regulation and the PHS Financial Conflicts of Interest Regulations. The Director of the Office of Research Compliance Administration has delegated authority to implement the requirements of this Regulation on behalf of the Institutional Official.

1.3. Administrative Action and Sanctions. The Institutional Official may suspend all relevant activities until a Financial Conflict of Interest, as defined below, is managed or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of this Regulation or other applicable policies on Conflicts of Interest or federal law also may constitute cause for disciplinary or other administrative action pursuant to applicable Institutional policy, including, and up to, termination from employment or expulsion from enrollment. (See Section 6).

1.4. Conflicts of Interest. This Regulation 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 Regulation informs Investigators, including, but not limited to, faculty and students, 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 Regulation. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the supervisor or the Institutional Official or designee.

2. Definitions

2.1. Conflict of Interest Committee means the Institution's committee that advises the Institutional Official on conflict of interest matters. If a committee advises the Institutional Official, it will consist of at least the Director of the Office of Research Compliance Administration (ORCA), the Associate Vice Chancellor for Research and Graduate Studies, and the appropriate Associate Dean for Research or other administrator designated by the Dean within an academic college or the Investigator's supervising department head (or comparable position, if Investigator's appointment resides outside of an academic department).

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

2.3. Disclosure of Significant Financial Interest means an Investigator's disclosure of significant financial interest to the Institutional Official or designee.

2.4. 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. 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.

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.
- e) 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.

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

2.5.1. With regard to any publicly traded entity, the value of any remuneration (including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)) received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest (including any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000; or

2.5.2. With regard to any non-publicly traded entity, the value of any remuneration (including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)) received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000; or

2.5.3. With regard to any non-publicly-traded company, the Investigator or his or her Family holds any equity interest (at any time); or

2.5.4. Intellectual Property Rights (e.g. patents, copyrights, etc.) and Interests, upon receipt of income related to such rights and interests, provided, however, income derived from intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are not a Financial Interest (See Section 2.4, above).

2.6. 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.

2.7. Financial Conflict of Interest Report means the Institution's report of a financial conflict of interest to a PHS Awarding Component (i.e., the organizational unit of the PHS that funds the research that is subject to the PHS Financial Conflicts of Interest regulations).

2.8. Institution means East Carolina University.

2.9. 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 Regulation, the Institutional Official is designated as the Vice Chancellor for Research and Graduate Studies.

2.10. Institutional Responsibilities has the same meaning as "University Employment Responsibilities" as

defined at UNC Policy 300.2.2(l)(E) and includes "Primary Duties" and "Secondary Duties." Primary Duties consist of assigned teaching, scholarship, research, institutional service requirements, patient care, 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.

2.11. Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposed 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, but is not limited to, postdoctoral associates, scientists, clinical and technical staff regardless of classification, or students. The definition may also include collaborators or consultants as appropriate.

2.12. Manage means taking action to address a financial conflict of interest, which can include, but is not limited to, reducing or eliminating the financial conflict of interest, to ensure, to the extent possible that the design, conduct, and reporting of research will be objective and free from bias.

2.13. PI/PD means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator, as defined herein.

2.14. 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.

2.15. 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). Further, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement or contract, including, but not limited to, a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or resources award.

2.16. Senior/key personnel means, with regard to PHS funding by means of a grant or a cooperative agreement, the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS by the Institution, and, with regard to PHS funding by means of a contract, the PD/PI and any other personnel considered to be essential to work performance in accordance with the HHS Acquisition Regulation subpart 352.242-70 and identified as key personnel in the contract proposal and contract.

3. Disclosure of Financial Interests. All Investigators are required to disclose their significant financial interests to the Institution on an annual and ad hoc basis, as described below. The Institutional Official, or his or her designee, 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.

3.1. Annual Disclosures. All Investigators must disclose their Significant Financial Interests and those of their Family to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by June 30 for the previous year.

3.2. Ad hoc Disclosures.

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

3.2.2. Prior to applying for PHS funded research, 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 and those of the Investigator's Family. The Institution will not submit a research proposal unless the Investigator(s) has(have) submitted and appropriately managed such ad hoc disclosures. Further, there may be no expenditure of funds under a new PHS-funded research project until the Institutional Official has reviewed all Investigator disclosures of significant financial interests and managed any Financial Conflicts of Interests.

3.2.3. In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they or their Family acquire during the course of the year within thirty (30) calendar days of discovering or acquiring the Significant Financial Interest. This requirement includes Investigators who are new to participating in a PHS-funded research project as well as Investigators who are already participating in the project. Such disclosures shall be reviewed, and any associated financial conflicts of interest shall be managed, in a timeframe and manner compliant with the federal regulations on Financial Conflicts of Interest (i.e., within sixty (60) days). Depending on the nature of the Significant Financial Interest, the IO may determine that additional interim measures are necessary with regard to an Investigator's participation in a PHS-funded research project between the date of disclosure and the completion of the review of that disclosure. The IO has authority to implement such measures.

3.3. Travel.

3.3.1. Investigators also must 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 or his or her designee 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.

3.3.2. Note that not all University-related travel must be disclosed. Exclusions from this requirement may be found in Section 2.4(e), above.

4. Review and Decision of the Institutional Official.

4.1. Guidelines. The following guidelines shall be used by the Institutional Official to determine whether an Investigator's significant financial interest is related to PHS funded research and, if so related, whether the significant financial interest is a financial conflict of interest:

4.1.1. 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 is related to PHS-funded research and, if so, whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage, reduce, or eliminate the conflict, as appropriate and consistent with the PHS FCOI Regulations.

4.1.2. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official, reasonably determines that the significant financial interest:

4.1.2.1. Could be affected by the PHS-funded research; or

4.1.2.2. Is in an entity whose financial interest could be affected by the research

4.1.2.3. The Institution may involve the Investigator in the designated official's determination of whether a significant financial interest is related to the PHS-funded research.

4.1.3. A Financial Conflict of Interest will be deemed to 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.

4.1.4. 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 moves forward. The affected Investigator or the COI Committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

4.2. 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.

5. Reporting to PHS.

5.1. Should any Financial Conflict of Interest or instance of non-compliance be required to be reported to PHS/NIH, the Institutional Official will report in accordance with applicable PHS regulations (See e.g., 42 C.F.R. § 50.605 and 45 C.F.R. § 94.5). 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.

6. Investigator Non-Compliance.

6.1. Retrospective Review.

6.1.1. 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 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. Such review shall be completed in a manner and within a timeframe compliant with the PHS Financial Conflicts of Interest regulations (i.e., within 120 days).

6.1.2. 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.

6.1.3. 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.

6.1.4. In any case in which the United States Department of Health and Human Services, or any component thereof with delegated authority, 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 an Investigator with a financial conflict of interest that was not managed or

reported by the Institution as required by the PHS Conflicts of Interest regulations, the Investigator involved shall disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

6.2. Disciplinary Action.

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

6.2.2. An Institutional Official's decision to take remedial action because of an Investigator's failure to comply with this Regulation, 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.

6.2.3. In addition to those remedial actions undertaken by the Institutional Official pursuant to Section 6.2.1, the Institutional Official may refer any instance of Investigator non-compliance to the appropriate Vice Chancellor or other administrator for disciplinary action in accordance with applicable University policies.

7. Training. Each Investigator, including any Investigator new to the Institution, must complete training on this Regulation and on the PHS Financial Conflicts of Interest regulations prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators also must complete training immediately in the event that this Regulation is substantively amended in a manner that affects the requirements of Investigators (typically within sixty (60) days), or if it is determined that the Investigator has not complied with this Regulation or with a management plan related to their activities (typically within thirty (30) days), or if an Investigator is new to the Institution (typically within sixty (60) days). "Immediately" is defined to be within a reasonable timeframe that reflects that it is a priority that Investigators comply with the requirements of this Regulation and applicable law. The Institutional Official may specify an appropriate timeframe for training where immediate training is required. For purposes of this Regulation, all PHS-funded Investigators must complete the on-line PHS-COI training utility made available through the Office of Research Compliance Administration (and which may include PHS training modules available at <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> (<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>)). Self-directed training is offered by Public Health Service agencies and is highly encouraged as a supplement to the required on-line training.

8. Subrecipients. If PHS funded research is carried out through a subrecipient (e.g., subcontractors or consortium members), then the Institutional Official shall take reasonable steps to ensure that any subrecipient Investigator complies with requirements of the PHS Financial Conflicts of Interest regulation in a manner consistent with 45 CFR 50.604(c). This includes providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of any funds and within sixty (60) calendar days of any subsequently identified FCOI. The Office of Sponsored Programs shall ensure that any subrecipient agreements comply with the requirements of 42 CFR 604(c).

9. Record Retention. The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three (3) years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

10. Confidentiality and Personnel File. 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. The confidentiality of personnel files is governed by N.C. Gen. Stat. § 126-22.

11. Public Accessibility. Prior to the expenditure of any funds under a PHS-funded research project, the Institution will respond to any requestor within five (5) business days of the request, and provide information concerning any Significant Financial Interest disclosed to the Institution by senior/key personnel that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior/key personnel;
- 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 regulation.

Requests should be submitted to the Director of the Office of Research Compliance Administration at:

Director, Office of Research Compliance Administration

2200 South Charles Blvd.

East Carolina University

Greenville, NC 27858-4353

12. 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.

East Carolina University

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