

3-3-402 Conflict of Interest.

3-3-402(1) Financial Conflict of Interest Pertaining to Sponsored Projects.

This policy sets forth procedures and guidelines that are to be followed in disclosing and resolving actual and potential faculty and staff conflicts of interest pertaining to externally funded projects conducted, sponsored, or administered by the University, including where the University has subcontracted or intends to subcontract to an external organization under one of the University's sponsored projects.

The University and its faculty and staff often benefit from participation in both public and private outside activities. The University has no interest in setting forth detailed rules that may interfere with faculty and staff members' legitimate outside interests that do not conflict with requirements of applicable Federal and/or State statutes or regulations.

Faculty and staff members, in turn, must ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to the University. This obligation pertains to both full-time and part-time faculty and staff as well as to students who are employed on externally funded projects.

This regulation does not alter or amend Board Policy 1-1-502 (Conflicts of Interest) applicable to all University employees.

(a) Definitions.

- I. Financial Conflict of Interest (FCOI): a significant financial interest (see XI below) that is reasonably determined by the Designated Institutional Official (see III below) to be related to federally funded scholarship and that could directly and significantly affect the design, conduct, or reporting of research, educational, or other activities funded by an external sponsor. The institution is required to review each Investigator SFI disclosure to determine if a SFI:
 - a. For PHS/NIH-funded research:
 - i. is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research)
and
 - ii. could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.
- II. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.
- III. Designated Institutional Official (DIO): the individual designated by the University to solicit and review disclosures of Significant Financial Interest from Investigators/Senior Key Personnel, and who oversees the process of managing and reporting Financial Conflicts of Interest. The University has designated the Assistant Vice President for Research (AVPR) to serve as DIO. If, for whatever reason, the AVPR is unable to assume this role, the Chief Academic Officer will appoint another UNC employee with research expertise to serve in this capacity.
- IV. Institutional Responsibilities: those professional responsibilities an investigator has by virtue of being a UNC employee, including, but not limited to,

research/scholarship/creative works, teaching, service, consultation, professional practice, performance, management and administrative duties.

- V. Investigator: the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or other educational activities funded by an external sponsor or proposed for such funding (this may include collaborators or consultants.)
- VI. Senior Key Personnel: any individuals identified as contributing to the scientific/scholarly development or execution of a project in a substantive, measurable way, including the program director/principal investigator and other individuals designated as such in the sponsored scholarship application, progress report, or any other report submitted to the funding agency
- VII. Manage: taking action to address an FCOI
- VIII. NSF: National Science Foundation
- IX. PHS: Public Health Service of the U.S. Department of Health and Human Services, and [any components of the PHS](#), including the National Institutes of Health (NIH)
- X. Research/Scholarship: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research and product development
- XI. Significant Financial Interest: Financial Interest (see II, above) of Senior/Key Personnel, aggregated with those of the Senior/Key Personnel's spouse and dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities (see IV, above), and where:

(A) With respect to PHS funded projects, a Significant Financial Interest exists if:

- (i) the value of any remuneration received from a publicly traded entity in the twelve months preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds **\$5,000**. Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, or paid authorships. 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; **or**
- (ii) the value of any remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds **\$5,000**, or when the senior/key personnel, or their spouse or dependent children, holds any equity interest such as stock, stock options, or other ownership interests; **or**
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon the receipt of income exceeding **\$5,000** related to such rights and interests that is not reimbursed through UNC)

or

(B) With respect to NSF funded projects, a Significant Financial Interest exists if:

- (i) the value of any equity interest that, when aggregated for the senior/key personnel and their spouse and dependent children, exceeds **\$10,000** as determined through reference to public prices or other reasonable measures of fair market value, and represents more than a **5% ownership** interest in any single entity. **or**
- (ii) the value of any salary, royalties, or other payments received in the twelve months preceding the disclosure that, when aggregated for the senior/key personnel and their spouse and dependent children, are expected to exceed **\$10,000**.

or

(C) With respect to projects funded by other external entities, a Significant Financial Interest exists if:

The senior/key personnel (or their spouse or dependent children) is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation that is funding a sponsored project or is providing goods and services under a sponsored project on which the Investigator is participating;

however,

(D) A Significant Financial interest does not include:

- I. salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator 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.
- II. any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization.
- III. 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.
- IV. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States” or a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a domestic/U.S. institution of higher education; or
- V. income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States” or a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a domestic/U.S. institution of higher education.

****Note**, disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. Senior/key personnel must disclose all foreign financial interests (which includes income from seminars,

lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure as defined above.

(b) Guidelines for Determining Relatedness of Significant Financial Interests and Existence of FCOI

A financial conflict of interest exists when the institution's designated official(s) (DIO) reasonably determine(s) that the [significant financial interest \(SFI\)](#) of the Senior/Key Personnel, and/or those of their spouse and dependent children, could directly and significantly affect the design, conduct, or reporting of the federally-funded research. The DIO or an official designee will review all SFI disclosures related to the Senior/Key Personnel's institutional responsibilities to determine whether an FCOI exists prior to the expenditure of any funds awarded. The relatedness of SFI in the determination of an FCOI is determined by review by the DIO on behalf of the University of all information provided by the Senior/Key Personnel. When determining whether the SFI represents an FCOI, the DIO will consider the following:

- Could the SFI affect the investigator's institutional responsibilities?
- Could the SFI be affected by the research/scholarship?
- Is the SFI an entity whose financial interest could be affected by the research/scholarship?
- Could the SFI directly and significantly affect the experimental design, conduct, or reporting of the federally funded research.

When providing information for review, the Senior/Key Personnel must address two points with regard to themselves, their spouse and dependent children to determine if an FCOI as it relates to the funded research/scholarship exists.

- Define the institutional responsibilities of the investigator (i.e., teaching, research/scholarship, service, administration, clinical responsibilities, etc.)
- Describe SFIs related to the defined institutional responsibilities

The DIO may involve the Investigator in making these determinations, and they may convene the Conflict Review Committee (CRC) to assist in the review and determination process.

(c) Disclosure of Significant Financial Interests

An investigator is responsible for disclosing any financial or related interest that could present an FCOI as noted in subsection (a.X.(A)), above. Disclosure is an important legal requirement and a key factor in protecting an investigator's reputation and career from potentially embarrassing or harmful allegations of misconduct.

- (1) All investigators/Senior Key Personnel must disclose their Significant Financial Interests to the University, through the DIO or designee, prior to

submission of an external proposal. The University will not submit a proposal unless all Investigators have submitted such disclosures.

- (II) Pertaining to PHS funded projects: regardless of when the initial disclosure was made, all investigators must submit annual disclosure updates during the annual COI disclosure window. The UNC annual COI process is communicated to campus via email and typically occurs in October every year.
- (III) Pertaining to all sponsored projects: Investigators/Senior Key Personnel must submit updates within 30 days of discovering or acquiring any new or previously undisclosed Significant Financial Interests

(d) Travel Disclosure

- (I) Senior/Key Personnel must disclose travel that is related to their Institutional Responsibilities and is paid on behalf of or reimbursed to the Investigator when cost or reimbursement is **\$5000 or greater**, excluding travel that was paid by a federal, state, or local government agency located in the United States or a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an a United States institution of higher education.
- (II) Travel 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.
- (III) The DIO will determine if additional information is needed to determine whether the travel constitutes an FCOI with the Investigator's sponsored project.

(e) Review and Determination

- (I) If a disclosure reveals a Significant Financial Interest, it will be reviewed promptly by the DIO or designee for a determination of whether it constitutes an FCOI. If it is determined that an FCOI exists, the DIO with guidance from the Conflict Review Committee (CRC), will take action to eliminate, reduce, or manage the conflict, as appropriate. (see (f) Sanctions for possible outcomes to resolve FCOI)
- (II) The CRC is comprised of at least one faculty member designated by the chair of the Faculty Senate; an administrator designated by the Chief Academic Officer, and the Chief Research Officer/Associate Vice President for Research or their designee and is advised by the University's legal counsel.
- (III) In reviewing disclosures, the DIO and the CRC will be guided by the following practices and apply them as appropriate:
 - (A) Assure adherence to the requirements of applicable Federal and/or State statutes and/or regulations and relevant policies contained in the Board of Trustees Policy Manual and the University Regulations.
 - (B) Consider the nature and extent of the financial interest and the relationship of the Investigator and the external organization.

- (C) Give full consideration to the project proposal and/or the terms and conditions of sponsored awards that may inform the reasonable determination of whether an FCOI exists, including any mitigating or complicating factors.
 - (D) Consult with, and obtain additional information from, the Investigator as may be helpful in determining whether an FCOI exists.
 - (E) Act in a timely manner so as not to unduly delay the conduct of the project.
- (IV) An FCOI will exist when the DIO or designee, in consultation with the CRC, reasonably determines that an [investigator's significant financial interest \(SFI\)](#) could directly and significantly affect the design, conduct, or reporting of the externally funded research/scholarship.. If the DIO determines that there is an FCOI that can be managed, they must require and approve a written management plan before any related research or educational activities go forward. The affected Investigator in consultation with the CRC is responsible for developing and submitting a proposed management plan to the DIO for review and approval.

Conditions or restrictions that might be imposed to resolve the FCOI include, but are not limited to:

- i. public disclosure of Significant Financial Interests (e.g., when presenting or publishing the research; to staff members working on the project; to all students working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s); to research participants).
- ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
- iii. Appointment of an independent monitor with suitable knowledge of the project and capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest.
- iv. modification of the scope of work or research plan.
- v. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research reduction or elimination of the financial interest (e.g., sale of an equity interest).
- vi. severance of SFI relationships that create conflicts.

(f) Sanctions

Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating Investigator until the matter is resolved or other action deemed appropriate by the DIO is implemented. Sanctions may include:

- I. Required additional training or more frequent training.
- II. The inability to submit proposals to external funders, including PHS/NIH, NSF, and other external funders.
- III. Suspension of grant-related activities.

- IV. Loss of access to grant funds until all violations have been addressed.
- V. Repeated, willful violation may result in extended or permanent loss of privilege to submit external funding.

The DIO'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 DIO, will be described in a written explanation of the decision to the Investigator, their unit leader, their dean, the CRC, and if applicable, any other compliance bodies (e.g., the IRB, IACUC). The Investigator will also be informed of their right to appeal the decision.

(g) Appeal Procedure

If the Investigator is dissatisfied with a determination of an FCOI, they may appeal to the Faculty Grievance Committee and Chief Academic Officer (CAO) or their designee who will consult with the Investigator, the DIO and the CRC as they deem necessary and appropriate to the particular circumstance. The decision of the CAO will be final.

(h) Retrospective Review Pertaining to PHS Projects

If during the course of ongoing externally-funded research/scholarly activity, the DIO, their designee, or the CRC determines that an SFI was not disclosed, reviewed, or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest; failure by an Investigator to materially comply with a management plan for an FCOI; or failure of the DIO, their designee or the CRC to review SFI to determine the existence of an FCOI the DIO, their designee, and/or the CRC will complete a retrospective review within 60 days to determine whether it is related to the externally funded activity and whether an FCOI exists with respect to the Investigator's activities and the sponsored project. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be an FCOI, or the DIO, their designee, or the CRC did not review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, UNC must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS Research Activities. The purpose of this retrospective review is to determine if the ongoing PHS Research Activity was biased in its design, conduct or reporting. Documentation of the retrospective review will include the PHS project number, the OSP award number, project title, PI/PD, name of the Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that UNC will take to manage the identified FCOI.

If bias is found, the Institution must notify the sponsor promptly and submit a mitigation report. If the FCOI was previously reported to the sponsor, the mitigation report is submitted as a "Revised FCOI Report", as defined by NIH. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

(i) Training

All Investigators must complete training on financial conflict of interest prior to engaging in work funded by the PHS, NSF, or other external sponsor, and at least every four years throughout the duration of the funded award; whenever an investigator is not in compliance with this policy or has failed to comply with a management or mitigation plan; in the event that this policy is substantively amended in a manner that affects the requirements of Investigators; or is new to UNC. Training will include the following

- I. informing investigators/faculty of the FCOI policy with hire and at least annually at the initiation of the annual FCOI Disclosure Exercise. The policy will also be posted on the website.
- II. Information regarding UNC institutional disclosure requirements for faculty/investigators with hire; at least annually at the initiation of the annual FCOI Disclosure Exercise; and prior to submission to PHS, NSF, other external funders; and
- III. All investigators/Senior Key Personnel must provide documented completion of training of PHS regulations, either through the appropriate CITI module or the NIH FCOI module found on the NIH training website. Documentation will be associated with the investigators COI declaration in our research platform (Streamlyne)

(j) Record Access and Retention

The DIO or designee 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 sponsor or the prime sponsor awardee or until the resolution of any sponsors' actions involving the records, whichever is longer. For Federal awards that are renewed quarterly or annually, records will be retained for three years from the date of the submission of the quarterly or annual financial report, respectively, as reported to the awarding agency or pass-through entity in the case of a subrecipient. HHS awarding agencies and pass-through entities must not impose any other record retention requirements upon non-Federal entities.

To the extent permitted by law, all such records will be maintained in strict confidence. However, the University may make such information available to an agency funding the work, to a requestor of information concerning an FCOI related to PHS funding, or to the primary entity who made the funding available to the University, if requested or required. If the University is requested to provide disclosure forms or related documents to an outside entity, the Investigator will be informed.

- (I) PHS regulations require that the University respond within 5 business days to any request for information about SFIs held by Key Personnel when UNC has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs.
- (II) The information provided in the disclosure forms may be released or transmitted to PHS upon request. Completed disclosure forms also may be released in response to a public records request, pursuant to the terms of the Colorado Public Records law.
- (III) Records of financial disclosures, Designated Institutional Official's determinations, Conflict of Interest Committee recommendations, and University

actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

(k) Public Accessibility Pertaining to PHS Funded Projects

Prior to the expenditure of awarded funds, the University will publish on a website that is accessible to the public, information concerning any Significant Financial Interest that meets the following criteria:

- (I) Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel.
- (II) a determination has been made that the Significant Financial Interest is related to the PHS-funded work; and
- (III) A determination has been made that the Significant Financial Interest is FCOI. The information to be made available will be consistent with the requirements of the PHS regulations.

(l) Reporting

- (I) Pertaining to PHS Projects: Initial reports of FCOI must be made to PHS prior to the expenditure of any funds provided under a PHS Research Activity. UNC is not required to submit a report to PHS if conflicts of interest are eliminated before research funds are expended. If the funding for the project was made available from a prime PHS-awardee, such reporting will be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Additional FCOI reports must be submitted by the DIO or their designee to PHS/NIH under the following circumstances:

- a. Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (either through extension notification or an NIH prior approval request). When during the course of an ongoing PHS Research Activity an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
- b. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS Research Activity.
- c. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing PHS Research Activity.
- d. Following a retrospective review (for details, see sections **(h)** above) to update a previously submitted report, if new information is discovered following completion of the review.

- (II) Pertaining to NSF Projects: If the DIO finds that the University is unable to satisfactorily manage an FCOI, they will inform the NSF Office of the General Counsel as required by NSF.

(m) Sub-recipient Compliance Pertaining to PHS and NSF Funded Projects

I. For PHS/NIH Funded Projects

- a. UNC is responsible for ensuring any subrecipient's compliance with the FCOI regulation and reporting identified FCOI for subrecipient Investigators to the NIH. When Primary on a grant, UNC must incorporate as part of a written agreement with a subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.
- b. If a subrecipient Institution relies on their FCOI policy, they must report identified FCOIs to UNC in sufficient time to allow UNC to report the FCOI to the NIH to meet reporting obligations.
- c. If a subrecipient institution relies on UNC's FCOI policy, they must submit all Senior Key Personnel disclosures of SFI to UNC in sufficient time to allow for the review, management, and reporting of identified FCOIs to the NIH.
- d. UNC is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

II. For NSF Funded Projects

(n) Conflicting Requirements

Should an external sponsor have requirements regarding disclosure and management of FCOIs that differ from this policy, the sponsor's requirement will prevail.