



Policy Chapter: Chapter 13 Research

Policy Number and Title: 13.005 Conflict of Interest for Sponsored Projects

I. Policy Statement

It is the policy of UNT that no proposed, awarded, or ongoing UNT research project be biased by a significant financial interest of any Investigator responsible for the design, conduct, or reporting of the research. The purpose of this policy is to assure objectivity in research.

All UNT Investigators who apply for or receive funding from any entity for a research project will comply with the requirements of this policy and the UNT conflict of interest procedures for Public Health Services (PHS) funded research or non-PHS funded research, as applicable.

This policy will provide assurance to investigators, UNT, sponsors of institutional research, and most importantly the public, that research activities at UNT will be conducted in a manner consistent with institutional and public values.

II. Application of Policy

All UNT personnel, including, but not limited to, administrators, faculty, staff, post-doctoral fellows, or students, whose institutional responsibilities include the design, conduct, or reporting of research, either funded or proposed for funding.

III. Policy Definitions

A. Entity

“Entity,” in this policy, means any corporation, business, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, joint stock company, receivership, trust, individual, natural person, foreign academic institution or government, or any other for-profit commercial operation, but excluding UNT. An Entity also includes organizations where UNT may participate on the Entity’s board of directors or hold stock in the Entity; any not-for-profit organization acting, directly or indirectly, as an agent for, a commercial organization; or any other legal concern organized for profit or charitable purposes.

B. Financial Conflict of Interest (FCOI)

“Financial Conflict of Interest,” in this policy, means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

C. Institutional Responsibilities

“Institutional Responsibilities,” in this policy, means an Investigator’s professional responsibilities on behalf of UNT, which may include 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.

D. Investigator

“Investigator,” in this policy, means the Principal Investigator or project director and any

other person, regardless of title, position, or employment status, who is responsible for the design, conduct, or reporting of research externally funded or proposed for external funding. This may include, but is not limited to, faculty, staff, students, adjunct faculty, or sub-recipients (collaborators, consultants, contractors, or subcontractors).

E. Research

“Research,” in this policy, means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge.

F. Significant Financial Interest (SFI)

a. “Significant Financial Interest,” in this policy, means:

- i. For PHS funded research, 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:
- ii. Publicly Traded Entities. With regard to any publicly traded Entity, a SFI 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. 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.
- iii. Non-publicly Traded Entities. With regard to any non-publicly traded Entity, a SFI 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
- iv. Intellectual Property. Intellectual property rights and interests (e.g., patents, copyrights, royalties), upon receipt of income related to such rights and interests.
- v. Travel. Certain kinds of sponsored or reimbursed travel also constitute an significant financial interest. However, it may be impossible for an Investigator to make that determination, so Investigators covered by this policy must disclose to UNT the occurrence of any travel that is reimbursed or sponsored by any entity other than a Federal, state, or local government agency, a U.S. institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), a U.S. academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education. Travel that is funded or reimbursed through UNT (even if through an external grant) does NOT need to be disclosed to the Office of Research.
- vi. 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).

- b. For non-PHS funded research, anything of monetary value above \$5,000 paid by an Entity to the Investigator (or the Investigator's spouse or dependent children), including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- c. For both PHS funded research and non-PHS funded research, the term "Significant Financial Interest" does not include the following types of financial interests:
 - i. salary, royalties, or other remuneration paid by UNT to the Investigator if the Investigator is currently employed or otherwise appointed by UNT, including intellectual property rights assigned to UNT and agreements to share in royalties related to such rights;
 - ii. 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;
 - iii. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, a U.S. institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), a U.S. academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education; or
 - iv. income from service on advisory committees or review panels for a Federal, state, or local government agency, a U.S. institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), a U.S. academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education.

G. Spouse

"Spouse," in this policy, means a person in a legally recognized union of two individuals in a marital relationship, including a common law marriage as recognized by the law of the State of Texas.

IV. Policy Responsibilities

A. Conflict of Interest Responsibilities of Investigators

In addition to other responsibilities, as specified in this policy and the corresponding procedures, Investigators must be responsible for:

1. reading, understanding, and complying with this policy and with the corresponding procedures, as applicable;
2. informing all co-investigators, staff, students, contractors, sub recipients, and other individuals responsible for the design, conduct, or reporting of the Investigator's

- research of their obligation to comply with this policy;
3. cooperating with the office of Research Integrity and Compliance to ensure compliance with all requirements set forth in this policy;
 4. complying with the terms and conditions of applicable disclosures of Significant Financial Interest and conflict management plans as described in this policy and in the related procedures.

B. Conflict of Interest Review, Monitoring and Management

1. The Research Integrity Officer (RIO) will be appointed by the Vice President for Research & Innovation (VPRI) to administer the disclosure of Investigators' SFIs under this policy and the related procedures. The RIO has discretion to refer a disclosure of any SFI to the Conflict of Interest Review Committee (Committee) if the SFI has the potential to be categorized as an FCOI.
2. The VPRI will appoint the members of the Committee, which will consist of a least three (3) members from the UNT faculty, staff, or administration, with one member designated as Chair of the Committee.
3. The Committee will meet and determine if any referred SFI constitutes an FCOI and what modifications or conditions, if any, should be imposed to manage, reduce, or eliminate the FCOI.
4. The Committee may require the Investigator to submit more detailed information regarding the SFI that relates to the project proposed for funding or awarded and may require the Investigator to meet with the Committee. The Committee will take one of the following actions on each disclosure referred for review:
 - a. determine that an FCOI does not exist; or
 - b. determine that an FCOI does exist and
 - i. require modifications, conditions, or administrative oversight for the proposed project; or
 - ii. require withdrawal of the proposed project.
5. Examples of conditions or restrictions that might be imposed by the Committee include, but are not limited to:
 - a. public disclosure of FCOI (e.g., when presenting or publishing the research);
 - b. for research projects involving human subjects research, disclosure of FCOI directly to participants;
 - c. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

- d. modification of the research plan;
 - e. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f. reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - g. severance of relationships that create financial conflicts.
6. The Committee will notify the Investigator and the RIO of the Committee's decision in writing. If the Investigator does not agree with any modifications or conditions imposed by the Committee or with the Committee's recommendation that the proposed project be withdrawn, the Investigator will have ten (10) business days following receipt of such notice to appeal the decision to the VPRI. Within ten (10) business days of receipt of an appeal, the VPRI will notify the Investigator, the Committee, and the RIO of the VPRI's decision in writing. The decision of the VPRI will be final.
 7. A copy of any conflict management plan adopted by the Committee or by the VPRI (following an Investigator's appeal) will be maintained by the RIO. Any conditions or restrictions to resolve or manage conflicts of interest under the management plan must be implemented before UNT's expenditure of any funds awarded under a grant or contract.
 8. The Committee will monitor Investigator compliance with any implemented management plan on an ongoing basis until the completion of the funded project.

C. Maintenance of Records

The RIO will maintain records relating to all potential and/or alleged financial conflicts of interest, including but not limited to all records required to be maintained under [45 C.F.R. 75.361](#) and all Investigator disclosures of SFI and UNT's actions in response to such disclosures until the later of:

1. at least (3) three years from the date the final expenditures report is submitted to the funding agency, unless the funding agency requires another retention period;
2. the resolution of any governmental action involving such records;
3. the date specified by federal or state law; or
4. the UNT Records Retention Schedule.

D. Enforcement Mechanisms, Remedies & Noncompliance

1. The office of Research Integrity and Compliance must monitor Investigators and disclosures of conflicts of interest to determine compliance with this policy and related procedures.
2. Failure to comply with this Policy will be grounds for disciplinary action in accordance

with [UNT Policy 06.025, Faculty Misconduct and Discipline](#), for faculty members; [UNT Policy 05.033, Staff Employee Discipline and Involuntary Termination](#); and [UNT Policy 07.012, Code of Student Conduct](#) for students.

3. In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an financial conflict of interest that was not managed or reported by UNT as required by federal regulation, UNT must require the Investigator to disclose the conflict of interest in each public presentation of the results of research and request an addendum to previously published presentations to disclose the conflict of interest.
4. In addition, Investigators may also be subject to criminal sanctions or civil liability under federal or state law. Violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies. For PHS funded research, Investigators may also be subject to additional remedies as set out in the applicable Conflict of Interest procedure.

E. Public Accessibility

- a. The Office of Research and Integrity and Compliance will maintain an up-to-date, written, and enforced UNT policy and related procedures on financial conflicts of interest that comply with applicable regulations and will make this policy and related procedures available on the UNT website.
- b. Prior to the expenditure of funds, the UNT Research office in conjunction with the Office of General Counsel, will respond to any requestor within five business days of receiving a written request in a written response that makes available information concerning identified FCOIs held by an Investigator. This obligation only applies to significant financial interests related to PHS-funded research, when it is determined that the significant financial interest is a financial conflict of interest.
- c. Information made available to the public must be consistent with the requirements of applicable PHS or NSF policies.

F. Compliance Reporting

- a. Any suspected violation of this policy and related procedures must be reported to the RIO in Research Integrity and Compliance or to the Chief Compliance Officer in the Office of Compliance & Ethics.
- b. Investigators must disclose significant conflicts of interest, including those of a spouse or dependent, no later than at the time of application for funded research as well as at least annually during the period of an award and within thirty days of discovering or acquiring a new significant conflict of interest. The RIO will review these disclosures and will determine if a management plan is required or if other action must be taken in

accordance with this policy.

- c. For each federally funded project, the UNT Research Office must be responsible for submitting to the federal agency initial, annual and revised conflict of interest reports as required by federal regulation and in accordance with the following:
 - i. Prior to the expenditure of funds;
 - ii. Within 60 days of an Investigator who is newly participating in a project;
 - iii. Within 60 days for new, or newly identified, conflicts of interest for existing Investigators;
 - iv. At least annually until the project is completed;
 - v. Following a retrospective review to update a previously submitted report;
 - vi. Promptly if bias is found with the design, conduct or reporting of research (a mitigation report must be included if required);
 - vii. Promptly if an Investigator fails to comply with this policy or a management plan and appears to have been biased in the design, conduct or reporting of funded research.

G. Subrecipient Requirements

- a. For all subrecipients receiving funds under a UNT prime award for a sponsored project, the UNT Research Office will address, via a written agreement, whether the subrecipient will follow UNT's Policy 13.005, Conflict of Interest for Sponsored Project, or the financial conflict of interest policy of the subrecipient.
- b. Before a subrecipient's financial conflict of interest policy can be used, the UNT Research Office must obtain a certification from the subrecipient that its policy complies with [42 C.F.R. Part 50](#).
- c. In all subrecipient agreements, the UNT Research Office must include a requirement for the subrecipient to report identified conflicts of interest for its Investigators within a specified time frame in order to allow UNT to report to the federal agency as required. Alternatively, the UNT Research Office may include a requirement in the subrecipient agreement to review all subrecipient Investigator disclosures within a specified time period after they are made in order to be able to meet UNT's reporting obligations.

H. Training

- a. The UNT Research Office is responsible for establishing a process to inform each Investigator of this policy; the Investigator's disclosure responsibilities; and federal regulation related to conflict of interest.
- b. The UNT Research Office must require Investigators to complete conflict of interest training prior to engaging in research on a federally funded grant; at least every four

years; and immediately upon update of this policy when the requirements of Investigators are changed, when an Investigator is new to UNT and when an Investigator is found to be in non-compliance with a management plan.

V. Conflict of Commitment

This policy applies to conflicts of interest within the research setting. For guidance and reporting responsibilities for conflict of commitment, see [UNT Policy 05.008, Dual Employment and Other Activities](#).

VI. Resources/Forms/Tools

[Procedures for PHS or Non-PHS Disclosure](#)
[Research & Innovation Conflict of Interest Website](#)

VII. References and Cross-References

[20 U.S.C. 1001\(a\)](#)
[45 C.F.R. 75.361](#)
[42 C.F.R. Part 50, Subpart F, Promoting Objectivity in Research \(financial conflict of interest regulation\)](#)
[60 Fed. Reg. 35820, “Investigator Financial Disclosure Policy”](#)
[NSF Grant Policy Manual 95-26, Conflict of Interest Policies, Chapter V, GPM 510](#)
[Texas Government Code §§ 572.001-572.069](#)
[UNT Policy 05.008, Dual Employment and Other Activities](#)
[UNT Policy 05.033, Staff Employee Discipline and Involuntary Termination](#)
[UNT Policy 06.025, Faculty Misconduct and Discipline](#)
[UNT Policy 07.012, Code of Student Conduct](#)

VIII. Revision History

Policy Contact:	Director, Ethics & International Research Compliance
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Revisions:	01/01/2005, 08/01/2012, 09/01/2015, 08/29/2023, 12/20/2023* *non-substantive/formatting change