

Policies of the University of North Texas	Chapter 13
13.005 Conflict of Interest for Sponsored Projects	Research

Policy Statement. It is the policy of UNT that no proposed, awarded, or ongoing UNT research project shall 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 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.

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.

Definitions.

1. **Entity.** “Entity” means:
 - i. any corporation, business, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, joint stock company, receivership, trust, 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;
 - ii. 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.

2. **Financial Conflict of Interest (FCOI).** “Financial Conflict of Interest” means a Significant Financial Interest (SFI; as defined in the UNT conflict of interest procedure relevant to the funding entity) that could directly and significantly affect the design, conduct, or reporting of research.

3. Institutional Responsibilities. “Institutional Responsibilities” 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.
4. Investigator. “Investigator” 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).
5. Research. “Research” means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge.
6. Significant Financial Interest (SFI). For PHS funded research, “Significant Financial Interest” means:
 - i. 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:
 - (i) 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. 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;
 - (ii) 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

- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- ii. Certain kinds of sponsored or reimbursed travel also constitute an SFI. However, it may be impossible for an Investigator to make that determination, so Investigators covered by these procedures 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, 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. 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.

For non-PHS funded research, SFI means 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).

For both PHS funded research and non-PHS funded research, the term SFI **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, 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
- iv. 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.

7. Spouse. “Spouse” 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.

Procedures and Responsibilities.

1. Conflict of Interest Responsibilities of Investigators. In addition to other responsibilities as specified in this policy and the corresponding procedures, Investigators shall be responsible for:
 - i. reading, understanding and complying with this policy and with the corresponding procedures, as applicable;
 - ii. 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;
 - iii. cooperating with the Office of Research and Economic Development to ensure compliance with all requirements set forth in this policy;
 - iv. 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.

Responsible Party: Investigators

2. Management of Financial Conflicts of Interest. The Research Integrity Officer (“RIO”) will be appointed by the Vice President for Research & Economic Development to administer the disclosure of Investigators’ SFIs under this policy and the related procedures. The RIO at his/her discretion may refer a disclosure of any SFI to the Conflict of Interest Review Committee if the SFI has the potential to be categorized as an FCOI.

The Vice President for Research and Economic Development will appoint the members of the Conflict of Interest Review Committee, which will consist of a least three members from the UNT faculty, staff, or administration, with one member designated as Chair of the Committee.

The Committee will meet and determine if any referred SFI constitutes an FCOI and, if so, what modifications or conditions, if any, should be imposed to manage, reduce, or eliminate the FCOI.

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:

- i. determine that an FCOI does NOT exist;
- ii. determine that an FCOI DOES exist, and
 - (i) require modifications, conditions, or administrative oversight for the proposed project;
 - (ii) or require withdrawal of the proposed project.

Examples of conditions or restrictions that might be imposed by the Conflict of Interest Review Committee include, but are not limited to:

- i. Public disclosure of FCOI (e.g., when presenting or publishing the research);
- ii. For research projects involving human subjects research, disclosure of FCOI directly to participants;
- iii. 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;
- iv. Modification of the research plan;
- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- vii. Severance of relationships that create financial conflicts.

The Conflict of Interest Review Committee will notify the Investigator and the Research Integrity Officer 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 business days following receipt of such notice to appeal the decision to the UNT Vice President for Research and Economic Development. Within ten business days of receipt of an appeal, the Vice President for Research & Economic Development will notify the Investigator, the Conflict of Interest Review Committee, and the RIO of his or her decision in writing. The decision of the Vice President for Research and Economic Development will be final.

A copy of any conflict management plan adopted by the Conflict of Interest Review Committee or by the Vice President for Research and Economic Development (following an Investigator's appeal) will be maintained by the Research Integrity Officer. 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.

The Conflict of Interest Review Committee will monitor Investigator compliance with any implemented management plan on an ongoing basis until the completion of the funded project.

Responsible Party: Vice President for Research and Economic Development,
Research Integrity Officer, Conflict of Interest Review Committee

3. Maintenance of Records. The Research Integrity Officer will maintain records relating to all Investigator disclosures of Significant Financial Interests and UNT's actions in response to such disclosures until the later of: (1) at least 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.

Responsible Party: Research Integrity Officer

4. Enforcement Mechanisms, Remedies and Noncompliance. The Office of Research and Economic Development shall monitor Investigators and disclosures of conflicts of interest to determine compliance with this policy and related procedures.

Failure to comply with this Policy will be grounds for disciplinary action in accordance with UNT Policy 06.025 Faculty Discipline for faculty members, UNT Policy 05.033 Performance Counseling and Discipline for staff members, and UNT Policy 07.012 Code of Student Conduct for students.

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.

Responsible Party: Office of Research and Economic Development; Investigator; applicable supervisory official as specified in the Faculty Discipline Policy, the UNT Performance Counseling and Discipline Policy, or the UNT Code of Student Conduct Policy.

5. Public Accessibility. The Office of Research and Economic Development 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.

Responsible Party: Research Integrity Officer; Office of Research and Economic Development

6. Compliance Reporting. Any suspected violation of this policy and related procedures must be reported to the Research Integrity Officer in the Office of Research and Economic Development or to the Director of Institutional Compliance in the Office of Institutional Compliance.

Responsible Party: Research Integrity Officer, Director of Institutional Compliance

References and Cross-references.

UNT Policy 06.025 Faculty Discipline

UNT Policy 05.033 Performance Counseling and Discipline

UNT Policy 07.012 Code of Student Conduct

U.S. Public Health Service

“Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought,” 42 C.F.R. Part 50

National Science Foundation

“Investigator Financial Disclosure Policy,” 60 Fed. Reg. 35820

NSF Grant Policy Manual (NSF 95-26), Conflict of Interest Policies, Chapter V, GPM 510

Texas Government Code

“Personal Financial Disclosure, Standards of Conduct, and Conflict of Interest,” Chapter 572, TEX. GOV'T CODE ANN. Sec. 572.001 et seq.

Forms and Tools.

Procedures for PHS Disclosure:

http://research.unt.edu/sites/default/files/COI_Procedure_PHS.pdf

Procedures for Non-PHS Disclosure:

http://research.unt.edu/sites/default/files/COI_Procedure_Non-PHS.pdf

Website for Financial Conflict of Interest Disclosures and Forms:

<http://research.unt.edu/faculty-resources/research-integrity-and-compliance/financial-conflict-interest>

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*Definition only