

The University of North Texas at Dallas Policy Manual	Chapter 13.000
13.004 Research Conflict of Interest	Research

Policy Statement. It is the policy of the University of North Texas at Dallas that no proposed, awarded, or ongoing UNT Dallas research project shall be biased by significant financial interest or commitment of a UNT Dallas Investigator responsible for the design, conduct, or reporting of that research project. This policy is applicable to all UNT Dallas Investigators and applies to all research projects regardless of the source of funding. The purpose of this policy is to assure objectivity in research.

Texas state law has long included prohibitions against conflict of interest situations involving state faculty or staff members, including university faculty and staff. These laws are currently located in Chapter 572 of the Texas Government Code. Regulations issued by certain federal government agencies, such as the U.S. Public Health Service (PHS) and the National Science Foundation (NSF), require universities that apply for research funding to ensure that the objectivity of research will not be biased by any interest of an Investigator responsible for the research. This Policy should be read and applied in conjunction with applicable state law, federal regulations, and other UNT Dallas policies.

Growing interaction between for-profit enterprises and UNT Dallas has created new possibilities for the occurrence of conflicts of interest. These conflicts arise when there are opportunities for faculty or staff members to benefit financially either from the outcome of research or from activities conducted in the course of responsibilities as an institutional research member.

UNT Dallas believes that with clear guidelines and principles, in conjunction with appropriate supervision and monitoring, it is possible for interaction between industry and academia to take place in a manner that is consistent with the highest traditions of academic and scientific research and in a way that energizes scientific creativity.

This policy will provide assurance to UNT Dallas Investigators, UNT Dallas, and most importantly the public, that relationships with industry have been examined and will be conducted in a manner consistent with institutional and public values.

Application of Policy. All UNT Dallas Investigators who apply for external funding from any entity for a research project or educational activity shall comply with the requirements of this policy. If research at UNT is carried out through a subcontractor or collaborator, UNT shall require the subcontractor or collaborator to certify that all Investigators working on the project are in compliance with a conflict of interest policy that satisfies the requirements of this policy.

Definitions.

1. **Conflict of Interest.** “Conflict of Interest” means potential conflict of interest exists whenever an Investigator, his or her Family, or an Associated Entity of the Investigator possesses a material, decision-making or a Significant Financial Interest in a commercial or professional activity or Business that may impact a proposed, awarded or ongoing UNT Dallas research project involving the Investigator. The impact may occur in but is not limited to the areas of time, effort, finances, or focus of effort as related to research or adverse impact on a subordinate faculty or staff member. In general, a conflict of interest will be considered to exist whenever professional judgment concerning the performance of research duties or activities as an Investigator for UNT Dallas is unduly influenced by a secondary interest.
2. **Investigator.** “Investigator” means UNT Dallas faculty or staff members who are the principal Investigators or project directors, co-principal Investigators, as well as post-doctoral fellows, residents, technicians, students or any other faculty or staff member at UNT Dallas who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.
3. **NSF.** “NSF” means the National Science Foundation.
4. **PHS.** “PHS” means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services, and components of the U.S. Public Health Service to which the authority involved may be delegated.
5. **Significant Financial Interest.** “Significant Financial Interest” means anything of monetary value, 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). The term does not include:
 1. salary, royalties, or other remuneration from UNT Dallas; or
 2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; or
 3. income from service on advisory committees or review panels for public or nonprofit entities; or
 4. an equity interest that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

5. salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Procedures and Responsibilities.

When an Investigator submits a proposal for external funding of a research project or educational activity to the UNT Office of Research Services, the Investigator shall complete and provide to the UNT Associate Vice Provost for Research or other UNT designated official a "Significant Financial Interests Disclosure" form (the "disclosure"). In the disclosure, the Investigator shall indicate the general category of any Significant Financial Interests held by the Investigator, the Investigator's spouse, or his or her dependent children:

1. that would reasonably appear to be affected by the research or educational activity proposed for funding; or
2. in entities whose financial interests would reasonably appear to be affected by the research or educational activity proposed for funding.

For any categories marked, the Investigator shall attach to the disclosure supplemental documentation (in a sealed envelope marked "Confidential") that identifies the entity involved and the nature and the amount of the interest.

Responsible Party: UNT Dallas Investigator

If the Investigator does not disclose any Significant Financial Interests in the disclosure, the UNT Office of Research Services shall process the proposal in the ordinary manner unless there appears to be a Significant Financial Interest, in which case the Investigator will be contacted.

If the Investigator discloses any Significant Financial Interests in the disclosure, the UNT Associate Vice Provost for Research or other UNT designated official shall review the supporting documentation and the proposal to determine if there is a potential conflict of interest. If there is sufficient evidence to indicate a possible conflict of interest, the Associate Vice Provost for Research shall forward the disclosure, the supporting documentation, and the proposal to the UNT Conflict of Interest Review Committee (the "Committee") within five business days of receipt of the disclosure.

Responsible Party: UNT Office of Research Services; UNT Associate Vice Provost for Research or other UNT Designated Official

Within 10 business days of receipt of the disclosure, the Committee shall meet and determine whether the Significant Financial Interest(s) disclosed could directly and significantly affect the

design, conduct, or reporting of the proposed research or educational activity and determine what modifications or conditions, if any, should be imposed to manage, reduce, or eliminate such conflict of interest.

The Committee may require the Investigator to submit more detailed information regarding the Significant Financial Interest(s) that relates to the project proposed for funding and may require the Investigator to meet with the Committee. The Committee shall take one of the following actions on each proposal referred for review:

1. allow the proposal to go forward without modification;
2. require modifications, conditions, or administrative oversight for the proposed project;
or
3. recommend 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:

1. public disclosure of Significant Financial Interests;
2. monitoring of the research by independent reviewers;
3. modification of the research plan;
4. disqualification of the Investigator from participation in all or a portion of the research;
5. divestiture of Significant Financial Interests; or
6. severance of relationships that create actual or potential conflicts of interest.

The Committee shall notify the Investigator and the UNT Dallas Provost 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 shall have 10 business days following receipt of such notice to appeal the decision to the UNT Dallas Provost. The procedures for all such appeals shall be determined by the Committee.

Responsible Party: UNT Conflict of Interest Review Committee

Within 10 business days of receipt of an appeal, the UNT Dallas Provost shall notify the Investigator, the Committee, and the UNT Associate Vice Provost for Research or UNT

Designated Official of his or her decision in writing. The decision of the UNT Dallas Provost shall be final.

Responsible Party: UNT Dallas Provost

A copy of any conflict management plan adopted by the Committee or the UNT Dallas Provost shall be maintained in the records of the UNT Office of Research Services. Any conditions or restrictions to resolve or manage conflicts of interest must be implemented before UNT's expenditure of any funds awarded under a grant or contract involving the UNT Dallas Investigator.

Prior to the expenditure of any funds under a PHS award, UNT Office of Research Services shall report to the PHS awarding component the existence of a conflicting interest (but not the nature of the interest or other details) and assure that the interest has been managed, reduced or eliminated. For any conflicting interest identified subsequent to a PHS award, UNT Office of Research Services shall advise the PHS awarding component of the manner in which the conflict will be managed, reduced, or eliminated, at least on an interim basis, within 60 days of such identification. If the failure of an Investigator to comply with this policy has biased the design, conduct, or reporting of PHS-funded research, UNT Office of Research Services shall promptly notify the PHS awarding component of the corrective action taken or to be taken.

If a PHS-funded project involves evaluation of the safety or effectiveness of a drug, medical device, or treatment and the study has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed under this policy, the Investigator(s) involved must disclose the conflicting interest in each public presentation of the results of the research.

If UNT Office of Research Services is unable to satisfactorily manage a conflict of interest relating to NSF-funded research, UNT Office of Research Services shall notify the NSF of the circumstances.

The UNT Office of Research Services shall maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest until the later of: (1) a minimum of three years after the termination or completion of the award to which they relate; (2) the resolution of any governmental action involving those records; (3) the date specified by applicable federal or state law; or (4) the UNT Dallas Records Retention Schedule.

Responsible Party: UNT Office of Research Services

The Investigator must update the Disclosure on an annual basis during the period of the award and upon acquisition of any new reportable Significant Financial Interests. The Investigator shall submit a new Disclosure to the UNT Office of Research Services by August 31 of each year and within 30 days of obtaining a new financial interest that may be affected by the research or educational activity.

UNT Dallas anticipates that its Investigators will fully comply with this Policy. Failure to comply with this Policy will be grounds for disciplinary action in accordance with the Faculty Discipline Policy for faculty members, the Performance Counseling and Discipline Policy for staff members, and the Code of Student Conduct for students.

Responsible Party: UNT Dallas Investigator

Any suspected violation of this policy should be reported to the UNT Dallas Provost or to the UNT Compliance Office at www.unt.edu/compliance.

Responsible Party: UNT Dallas Faculty, Staff and Students

References and Cross-references.

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, Subpart F

“Responsible Prospective Contractors,” 45 C.F.R. Part 94

“NIH Grants Policy Statement,” National Institutes of Health, March 2001

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.

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