

Policies of the University of North Texas Health Science Center	Chapter 12
<b>12.101 Research Conflict of Interest</b>	Research

**Policy Statement**

It is the policy of the University of North Texas Health Science Center at Fort Worth (“UNTHSC”) that no proposed, awarded, or ongoing UNTHSC Research shall be biased by any conflicting interests of UNTHSC Investigators responsible for the design, conduct, or reporting of that Research. This policy is applicable to all UNTHSC Investigators and applies to all Research regardless of funding. The purpose of this policy is to assure objectivity in Research.

Texas state law has long included prohibitions against conflicts of interest involving state faculty or staff members, including university faculty and staff. These laws are located in Chapter 572 of the Texas Government Code. UNTHSC has adopted an Employee Ethics and Standard of Conduct Policy, as well as an Outside Employment & Other Activities Policy, that also address conflicts of interest (respectively policies 05.505 and 05.506 of UNTHSC Personnel Policies and Procedures Manual). 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 UNTHSC policies.

Growing interaction between industry and UNTHSC 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 either from the outcome of Research or from activities conducted in the course of fulfilling Institutional Responsibilities. UNTHSC 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 medical and scientific Research and in a way that energizes scientific creativity.

Investigators are expected to make reasonable inquiry as to whether their relationships and activities fall within the provisions of this Policy. It is not the intent of this Policy to eliminate or prohibit all situations involving a potential conflict of interest. This Policy is intended to enable Investigators to recognize situations that may pose a conflict of interest, to report these situations to the Research Conflict of Interest Committee (“RCOI Committee”), and to ensure that the RCOI Committee reviews, supervises or monitors these situations, where necessary. An integral part of this Policy is an annual disclosure mechanism whereby Investigators regularly review their activities. This Policy is intended to maintain the professional autonomy of scientists and physicians inherent in the self-regulation of science.

This Policy will provide assurance to the Investigators, UNTHSC, sponsors of institutional Research, and most importantly the public, that relationships with industry have been examined and that related research activities will be conducted in a manner consistent with institutional and public values.

**Application of Policy**

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

## **Definitions**

1. **Entity** – means
  1. 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 UNTHSC. An Entity also includes organizations where UNTHSC may participate on the Entity's board of directors or hold stock in the Entity;
  2. any not-for-profit organization acting, directly or indirectly, as an agent for, a commercial organization; or
  3. any other legal concern organized for profit or charitable purposes.
  
2. **Conflict Management Plan** – means a formal document approved by the RCOI Committee that directs the Investigator's management of Financial Conflicts of Interest or other potential conflicts of interest.
  
3. **Financial Conflict of Interest** – means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.
  
4. **Institutional Responsibilities** – means an Investigator's professional responsibilities on behalf of UNTHSC, which may include activities such as Research, consulting, teaching, professional practice, institutional committee memberships, and service on panels such as data and safety monitoring boards.
  
5. **Investigator** - means a UNTHSC principal investigator, faculty member, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, funded, or proposed for funding, by an external sponsor. This may include Research assistants, project directors, lab personnel, collaborators or consultants.
  
6. **Relative** – means an Investigator's spouse, dependent children, and other family members living in the same household, together with all individuals related within the second degree of affinity or third degree of consanguinity.
  
7. **Research** - means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic, applied and clinical research, as well as product development. The term includes any such activity for which research funding is available or proposed from an external sponsor.
  
8. **Significant Financial Interest** – means any financial interests of an Investigator, the Investigator's

spouse, or the Investigator's dependent children that appear to be related to the Investigator's Research or Institutional Responsibilities, including:

1. salary or other income, whether for consulting, paid authorship, lecturing, travel, honoraria, service on an advisory board or for any other purpose paid by an Entity, when aggregated, exceeds \$5,000 in the twelve months preceding disclosure; or
2. any remuneration received from a publicly traded Entity in the twelve months preceding 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; or
3. any remuneration received from a non-publicly traded Entity in the twelve months preceding disclosure that in aggregate exceeds \$5,000, or any equity interest held by the Investigator in such Entity, regardless of amount; or
4. any intellectual property rights and interests (patents, copyrights, trademarks) and income related to such rights and interests; or
5. service as an officer, manager, executive, member of a board of directors, or in any other fiduciary or managerial role for an Entity, whether or not remunerated; or
6. any occurrence of reimbursed or sponsored travel not reimbursed or sponsored by:
  - i. a federal, state, or local government agency,
  - ii. an Institution of higher education as defined at 20 U.S.C. 1001(a),
  - iii. an academic teaching hospital,
  - iv. a medical center, or
  - v. a research institute that is affiliated with an Institution of higher education.

A Significant Financial Interest does not include:

1. salary, or other remuneration paid by UNTHSC to the Investigator if the Investigator is currently employed or otherwise appointed by the UNTHSC;
2. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions;
3. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and
4. income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

## **Procedures and Responsibilities**

A potential conflict of interest may exist whenever an Investigator possesses, or the Investigator's spouse or dependent children possess, a Significant Financial Interest in an Entity that may impact proposed, awarded or ongoing UNTHSC Research involving the Investigator. However, potential conflicts of interest are not limited to financial interests. A potential conflict of interest may also exist whenever an Investigator, or a Relative of the Investigator, possesses an interest in an Entity that appears to be related to the Investigator's Institutional Responsibilities. In general, a potential conflict of interest will be considered to exist whenever professional judgment concerning the performance of Research or Institutional Responsibilities of an Investigator could be unduly influenced by a secondary interest. A potential conflict of interest also exists when Research will have a material adverse impact on institutional resources or on subordinate faculty, students and staff.

### **1. Disclosure and Review of Situations Involving Potential Conflicts of Interest**

In order to help in the identification of potential conflicts of interest, each Investigator shall be required to complete at least annually an "Annual Disclosure of Conflict of Interest Statement"

(hereinafter referred to as “Annual Disclosure Statement”) regardless of support. The Annual Disclosure Statement requires the Investigator to disclose any Significant Financial Interests, or other potential conflicts of interest that may be related to the Investigator’s Research or Institutional Responsibilities. The Annual Disclosure Statement shall be made on a form approved by the Office of Research. Throughout the year, the Annual Disclosure Statement must be amended by the Investigator to disclose material changes as well as new Significant Financial Interests or other potential conflicts of interest as they arise.

### Annual Disclosure Statement

Annual Disclosure Statements shall be submitted to the Office of Research by the first working day in October each year. Preliminary review of the Annual Disclosure Statement will be conducted by the Office of Research. Individual Investigators will be notified of any additional information and supporting documentation that is necessary to complete review of the Annual Disclosure Statement. Information necessary to complete the process shall be submitted within 15 calendar days from the date requested unless this time deadline is extended by the Office of Research. Regardless of review by the Office of Research, it remains the responsibility of the individual Investigator to fully disclose all relevant information on the Annual Disclosure Statement.

After the preliminary review, Annual Disclosure Statements will be divided into two categories by the Office of Research:

1. Annual Disclosure Statements that do not involve a Significant Financial Interest or other potential conflicts of interest will require no further review. Records will be maintained showing that a preliminary review has taken place and no further action is needed.
2. Annual Disclosure Statements that involve a potential Significant Financial Interest or other potential conflicts of interest will require full review and written approval by the RCOI Committee.

The Office of Research will inform the Investigator and the Investigator’s supervisor whenever an Annual Disclosure Statement is submitted to the RCOI Committee for review.

After conducting a full review, the RCOI Committee may make one of the following determinations:

1. No conflicts of interest exist;
2. A Financial Conflict of Interest or other potential conflict of interest exists and Investigator may conduct such Research only if the Investigator divests the conflicting interest or severs the relationship that creates the conflicting interest;
3. A Financial Conflict of Interest or other potential conflict of interest exists and, the Investigator must work with their supervisor to propose a Conflict Management Plan(s) for the identified conflict of interest(s) to ensure appropriate management of the conflict. The Conflict Management Plan must be acceptable to the RCOI Committee in order for the Research to proceed.

The RCOI Committee shall inform the Investigator and the Vice President for Research of its determination related to an Annual Disclosure Statement.

### Amendment to Annual Disclosure Statement

Throughout the year, Investigators are required to submit amended Annual Disclosure Statements

to the Office of Research within 30 days of discovering or acquiring a new Significant Financial Interest or other potential conflict of interest. An amended Annual Disclosure Statement must also be filed prior to any modification of a Conflict Management Plan. Amended Annual Disclosure Statements will be reviewed by the RCOI Committee in the same manner as Annual Disclosure Statements.

An amended Annual Disclosure Statement must be filed with the Office of Research within 30 days of the occurrence of any sponsored travel related to an Investigator's Research and Institutional Responsibilities that is not reimbursed through normal UNTHSC processes. At a minimum, Investigators will report the purpose of the sponsored travel, monetary value, the identity of the sponsor, the destination and the duration of the trip. However, an amended Annual Disclosure Statement is not required to be filed for travel that is reimbursed or sponsored by:

1. a federal, state, or local government agency,
2. an Institution of higher education,
3. an academic teaching hospital,
4. a medical center, or
5. a research institute that is affiliated with an institution of higher education.

Responsible Party: Investigator; Office of Research; RCOI Committee

## **2. The Research Conflict of Interest Committee**

A standing RCOI Committee shall consist of not less than five members and two alternate members. The RCOI Committee will consist of voting and non-voting members:

1. voting members will include: (i) representatives from UNTHSC colleges and schools; (ii) one or more representative from UNTHSC's Institutional Review Board; (iii) Vice President for Research or designee, who will only vote in the case of a tie; (iv) a designated individual from the Office of Research responsible for expedited reviews and determinations.
2. non-voting members will include: at least one representative from each of the following: Office of Technology Transfer & Commercialization and the Office of Grant & Contract Management.

The RCOI Committee will be appointed by the Vice President for Research. Members shall serve three-year terms, which will be staggered. Committee members shall elect a chair annually and may appoint an additional voting member as co-chair. Should any member fail to complete a term, the Vice President for Research shall appoint a replacement for the remainder of that member's term. The Vice President for Research may remove a committee member at any time for failure to perform committee duties adequately or as required to serve the best interests of the institution. A member shall recuse him or herself in areas where the member has a personal or professional interest. The UNT System Chancellor shall resolve any conflict of interest issues involving the President of UNTHSC.

The RCOI Committee will meet once a month for disclosure reviews, as needed. A quorum of three voting members is required for the RCOI Committee to perform its functions. Each member has one vote and decisions are to be made by a majority vote. The Vice President for Research shall resolve any ties in voting. The RCOI Committee chair along with a designated individual from the Office of Research may expeditiously review a disclosure and make a determination to ensure timely review. All expedited reviews will be reported to the RCOI Committee at the next convened meeting.

Responsible Party: Investigators; RCOI Committee; Office of Research, Vice President for Research

### **3. Responsibilities of the Research Office**

In addition to other responsibilities as specified in this policy, the Office of Research shall be responsible for:

1. providing Investigators with a copy of the UNTHSC Research Conflict of Interest Policy;
2. providing training on Financial Conflict of Interests to UNTHSC Investigators, which shall at a minimum meet all of the requirements of 45 CFR Part 94;
3. monitoring compliance of Investigators with the Annual Disclosure Statements, Conflict Management Plans and this policy;
4. performing a retrospective review of an Investigator's activities to determine whether Research was biased in design, conduct or reporting within 120 days of determining that the Investigator has failed to disclose a Significant Financial Interest or other potential conflict of interest or comply with an applicable Conflict Management Plan. This retrospective review shall be documented in accordance with 45 CFR Part 94; and
5. overseeing the establishment of adequate enforcement mechanisms to promote conformance with this policy.

Responsible Party: Office of Research

### **4. Responsibilities of Investigators**

In addition to other responsibilities as specified in this policy, UNTHSC Investigators shall be responsible for:

1. reading, understanding and complying with this Policy;
2. informing all co-investigators, staff, students, contractors, subrecipients, 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 RCOI Committee and the Office of Research to ensure compliance with all requirements set forth in this policy;
4. complying with the terms and conditions of Annual Disclosure Statements and Conflict Management Plans, including providing required annual status reports in a timely manner and updating information as needed; and
5. completing required initial and subsequent training at least every four (4) years or as determined to maintain compliance related to this Policy.

Responsible Party: Investigators

### **5. Research With Human Subjects**

In addition to the Annual Disclosure Statement required to be filed under this policy, Investigators who plan to participate in the design, conduct or reporting of human subjects research must submit individual, protocol – specific conflict of interest disclosure forms to the Office for the Protection of Human Subjects (OPHS). In the event that a Financial Conflict of Interest or other potential conflict of interest needs to be addressed, OPHS and the UNTHSC Institutional Review Board will manage

the potential conflicts as needed to comply with human subject protection policies and procedures. OPHS will forward OPHS and Institutional Review Board findings to the RCOI Committee for review.

Responsible Party: Investigator; Office for the Protection of Human Subjects; RCOI Committee

## 6. Sponsored Project Proposals

No sponsored project application may be submitted, no award may be finalized, and no account may be set up unless UNTHSC has received from each Investigator who would conduct Research under the proposal, current Annual Disclosure Statements. In addition, the Office of Grant & Contract Management will not set up sponsored project accounts until potential conflicts of interests have been managed or resolved to the satisfaction of the RCOI Committee. Investigators shall be responsible for confirming at the time of any proposal submission that their current Annual Disclosure Statement is accurate in regard to the proposal and shall be responsible for amending the Annual Disclosure Statement if it is not accurate in regard to the proposal.

The Office of Research will ensure compliance with all federal regulations that require certifications and reporting including that each application for funding to the PHS include specific certifications and agreements in regard to this policy and financial conflict of interest.

Investigators shall make the following certification to UNTHSC and to the granting agency prior to the submission of the grant proposal or contract application:

*“I have read and understand the University of North Texas Health Science Center Research Conflict of Interest Policy. I certify that this is a complete disclosure of all current Significant Financial Interests and other potential conflicts of interest related to my Research and Institutional Responsibilities. I have used all reasonable diligence in preparing this disclosure and it is, to the best of my knowledge, true and complete. I understand that I have a responsibility to immediately update the above information throughout the fiscal year or during the Research program period if my circumstances change. I will comply with any conditions or restrictions imposed by UNTHSC to manage, reduce or eliminate actual or potential conflicts of interest.”*

Responsible Party: Investigator; Office of Grant & Contract Management; Office of Research

## 7. Consulting Agreements Involving Employees

Investigators who are contemplating outside professional activities for which they will be paid, such as consulting, must submit a written request for approval to their supervisor in accordance with UNTHSC Personnel Policies 5.05 and 5.06. Faculty and staff members must exercise caution in entering into consulting agreements. Many such agreements provide that new inventions and ideas will be assigned to the company employing the faculty or staff member as a consultant. Care should be exercised to ensure that no UNTHSC facilities are used in any way in the performance of the consultant agreement and that the subject matter of inventions to be assigned to the company

pursuant to the consulting agreement is not within the scope of the Institutional Responsibilities of the faculty or staff member.

Rights in inventions within the scope of the faculty and staff member responsibilities to UNTHSC developed using UNTHSC's facilities or funding will be owned by UNTHSC pursuant to the UNTHSC Intellectual Property Policy irrespective of the terms of the consulting contract. Each consulting agreement must have written into it or attached to it the paragraph below recognizing UNTHSC's overriding rights:

*"The Company recognizes that the consultant is a faculty or staff member of the University of North Texas Health Science Center ("UNTHSC") (and as such, a faculty or staff member of the State of Texas), and has existing and overriding contractual obligations to UNTHSC. Nothing in this agreement shall be construed as requiring the consultant to violate those obligations. The Company specifically recognizes that the consultant has a contractual obligation to assign to UNTHSC all Intellectual Property pursuant to the UNTHSC Intellectual Property Policy that is related to the consultant's employment responsibilities to UNTHSC."*

Responsible Party: Investigator; Office of Technology Transfer & Commercialization

## 8. Educational Requirements

Investigators who are required to submit an Annual Disclosure Statement to UNTHSC must complete training on the UNTHSC Research Conflict of Interest Policy, procedures, and applicable federal regulations prior to engaging in applicable Research; thereafter, at least every four years; and immediately when any of the following circumstances apply:

1. UNTHSC revises its research conflict of interest policies or procedures in any manner that affects the Investigators;
2. a new Investigator moves to UNTHSC; or
3. UNTHSC finds that an Investigator is not in compliance with applicable federal regulations, the UNTHSC Research Conflict of Interest Policy, or a Conflict Management Plan.

Responsible Party: Investigator; Office of Research

## 9. Subrecipients

Subrecipients of UNTHSC Research funding that are not employed by or otherwise affiliated with UNTHSC must comply with this Policy. Subrecipients can comply in two ways:

1. A subrecipient may utilize the UNTHSC processes outlined in this policy to report and manage potential conflicts of interest. If the subrecipient is not employed by an institution that has enacted a policy in compliance with applicable federal rules and regulations, the subrecipient must contractually agree to submit to this policy and follow UNTHSC's requests for managing, reducing, or eliminating any conflicts. The agreement between UNTHSC and the subrecipient must include a requirement that the subrecipient disclose identified Financial Conflicts of Interest within a time period sufficient to allow UNTHSC to make reports required by federal regulation or,
2. If the subrecipient is employed by an institution that has enacted a conflict of interest policy that is in compliance with the applicable federal regulations, including 42 CFR 50 and 42 CFR 94 dated August 2012 or later, the subrecipient institution may provide written assurance that any conflicts related to the project under consideration have been managed, reduced or eliminated pursuant to

the institution's policy. A subrecipient's institution can provide the appropriate written assurances by submitting to UNTHSC a subrecipient form provided by the UNTHSC Office of Grant & Contract Management. Subrecipient institutions that rely on their own conflict of interest policy must contractually agree to report identified Financial Conflicts of Interests or other potential conflicts of interest to UNTHSC in reasonably sufficient time to allow UNTHSC to meet its reporting obligations.

Responsible Party: Investigator; Office of Grant & Contract Management; Office of Research

## 10. Reporting Obligations

For PHS funded Research, the Office of Research will be responsible for notifying the awarding component of the federal agency of the identification and management of any Financial Conflict of Interest within 60 days of the initial determination by the RCOI Committee that a Financial Conflict of Interest exists. For PHS funded and all other types of Research, if required by a federal or state agency or as determined appropriate by the Vice President for Research, the Office of Research will report any Financial Conflict of Interest or other potential conflict of interest to the funding source prior to expending any funds, and any interest identified as conflicting subsequent to the initial report will be reported within 60 calendar days of identification. If an Investigator's noncompliance with this policy may have biased the design, conduct or reporting of Research, the Office of Research will promptly notify the awarding agency of the corrective action taken or to be taken by the University, if required. For PHS funded research, the mitigation report will contain the information required under 45 CFR Part 94. Thereafter, the Office of Research will submit Financial Conflict of Interest reports annually, if required by federal or state law.

A copy of all notifications to external agencies will be kept in the Office of Research and in the Office of Grant & Contract Management's files to which the notification pertains.

For PHS funded Research, UNTHSC will make Financial Conflict of Interest information available within five business days to any requestor upon receipt of a written request. For all other types of Research, UNTHSC will make Financial Conflict of Interest information required to be released by law available within the time frame required by the Texas Public Information Act..

Responsible Party: Office of Research; Investigator; Office of Grant & Contract Management; Vice President for Research

## 11. Record Retention

If there is a federal requirement, all records related to disclosures and actions taken to manage potential conflicts of interest will be maintained for three (3) years from the date of submission of the final expenditure report at the completion of the award, for the time periods specified in 48 CFR part 4, subpart 4.7, or for the minimum amount of time required under UNTHSC's Record Retention Policy, whichever is longer. All other records related to disclosures and actions taken to manage potential conflicts of interest will be maintained for at least the minimum amount of time required under UNTHSC's Record Retention Policy or as otherwise required by federal or state law, whichever is longer. Retained records shall be made available to funding agencies for audit as required by federal and state law.

Responsible Party: Office of Research

## 12. Enforcement

The Office of Research shall conduct audits of Investigators and Annual Disclosure Statements to determine compliance with approved Conflict Management Plans on file and with this Policy.

The RCOI Committee will review all reported breaches of this Policy, including:

1. failure to make required disclosure(s);
2. incomplete or inaccurate information in any disclosure;
3. failure to update a disclosure when required to do so;
4. non-compliance with a Conflict Management Plan; or
5. non-compliance with any other directive of the RCOI Committee.

If the RCOI Committee concludes that a breach of this Policy has occurred, it will so notify the applicable Investigator in writing and such Investigator will be given the opportunity to respond in writing or in person to the RCOI Committee and take corrective action within a reasonable time period, typically 15 calendar days. If such corrective action is not taken within the specified time period, the RCOI Committee may recommend sanctions to the Vice President for Research.

Responsible Party: Office of Research; RCOI Committee; Vice President for Research; Investigator

## 13. Sanctions

The Vice President for Research, in consultation with the RCOI Committee, may recommend sanctions and disciplinary actions when an Investigator fails to disclose Significant Financial Interests or other potential conflicts of interest or otherwise fails to comply with this Policy. Sanctions may include a letter in a personnel file, restrictions on future submission of Research proposals, and other disciplinary actions up to and including dismissal in accordance with other UNTHSC policies. Recommendations of the Vice President for Research shall be made to the appropriate UNTHSC official depending on the status of an Investigator.

If a determination is made by a federal funding agency that clinical research funded by PHS 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 UNTHSC as required by federal regulation, then UNTHSC shall require the Investigator to 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 that address the Financial Conflict of Interest.

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.

Responsible Party: Vice President for Research

**References and Cross-references**

Chapter 572 of the Texas Government Code

05.505 Employee Ethics and Standards of Conduct

05.506 Outside Employment

42 CFR Part 50

45 CFR Part 94

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