

Policies of the University of North Texas Health Science Center	Chapter 12 – Research, IRB
12.101 Research Conflict of Interest	

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 project shall be biased by Significant Financial Interest or commitment of UNTHSC Investigator responsible for the design, conduct, or reporting of that research project. This policy is applicable to all UNTHSC 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. UNTHSC has adopted an Employee Ethics and Standard of Conduct Policy, as well as an Outside Employment & Other Activities Policy, that also address conflict of interest situations and are applicable to all UNTHSC faculty or staff members (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. To meet the requirements of these federal regulations, UNTHSC adopted a Conflict of Interest Policy on October 1, 1995. This Policy supersedes the 1995 Policy in its entirety and will become effective upon approval by the Board of Regents. This Policy should be read and applied in conjunction with applicable state law, federal regulations, and other UNTHSC policies.

Growing interaction between for-profit enterprises 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 financially either from the outcome of research or from activities conducted in the course of responsibilities as an institutional research member.

UNTHSC believes that with clear guidelines and principles, in conjunction with appropriate supervision and monitoring, it is possible for interaction between industry and academic medicine 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.

This Policy establishes guidelines for the appropriate structuring of relationships with industry and other outside ventures so as not to conflict with previously established responsibilities to UNTHSC. 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 Conflict of Interest Committee, and to ensure that the Conflict of Interest Committee reviews these situations and, if necessary, supervises or monitors them. An integral part of this Policy is a 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 should be viewed as complementing all institutional policies and procedures, including Sections 5.05 and 5.06 of UNTHSC's Personnel and Procedures Manual.

This Policy will provide assurance to the Investigators, UNTHSC, 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 Employees

Definitions.

Associated Entity - means any trust, organization or enterprise other than UNTHSC or any affiliate over which the Investigator, alone or together with his/her Family, possesses a material, decision-making or Significant Financial Interest.

Business - means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, Business or real estate trust, or any other legal entity organized for profit or charitable purposes, but excluding UNTHSC. A business also includes entities where UNTHSC may have participation on the Board of the Business or hold stock in the Business.

Clinical Research - means any research or procedure involving human subjects *in vitro* or the use of human samples for the development and evaluation of patient therapies such as diagnostic tests, drug therapies, or medical devices. It includes early clinical studies, evaluative research, epidemiological studies and clinical trials. It does not include an Investigator's participation in the design of a clinical study for which he is subsequently neither a participant nor an author.

Executive Position - refers to any position that includes responsibilities for a material segment of the operation or management of a Business.

Family - includes spouse, minor children, and other persons living in the same household, together with all individuals related within the second degree of affinity or third degree of consanguinity.

Investigator – means UNTHSC 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 UNTHSC who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

Participation - means to be part of the described activity in any capacity, including but not limited to serving as the principal Investigator, co-Investigator, research collaborator or provider of direct patient care. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of Clinical Research, to the trial participants unless they are in a position to influence the study's results or have privileged information as to the outcome.

Sponsored Research - means research, training and instructional projects involving funds, materials, or other compensation from external sources.

Significant Financial Interest –

- a. Receipt of, or the right or expectation to receive monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, payments for directorships or executive roles); equity interests (e.g. stocks, stock options, dividends or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights); or
- b. receipt of, or the right or expectation to receive other value, such as in the form of a forbearance, forgiveness, interest in real or personal property, rent, capital gain, real or personal property, or any other form of compensation, such as gifts.
- c. Notwithstanding the foregoing, for the purposes of this Policy, a “Significant Financial Interest” does not include interests held directly through funds such as mutual funds, pension funds, or other institutional investment fund in which the Investigator or the Investigator’s Family does not control the selection of investments. Further, the following financial interests do not rise to the level of a Significant Financial Interest: (1) salary, royalties, or other remuneration received from UNTHSC; (2) standard royalties received for published scholarly work or other professional writings; (3) royalties or equities received under UNTHSC royalty-sharing policies (see UNTHSC Intellectual Property Policy); (4) consulting fees received from an entity in which neither the Investigator, the Investigator’s Family, an Associated Entity of the Investigator, nor UNTHSC have any other relationship, provided that the consulting relationship has been approved in accordance with the UNTHSC Outside Employment Policy, and subject to all other policy requirements including appropriate devotion of time to UNTHSC; (5) income from seminars, lectures, or teaching engagements sponsored by public entities; or (6) income from services on advisory committees or review panels for governmental entities.

Procedures and Responsibilities.

Procedure / Duty

Responsible Party

A 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 UNTHSC 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 UNTHSC is unduly influenced by a secondary interest.

Faculty

GUIDELINES APPLICABLE TO POTENTIAL CONFLICT OF INTEREST SITUATIONS

Faculty

The following are representative categories of relationships and activities where conflicts of interest may arise that are subject to this policy. These classifications are representative only and are not intended to define absolute categories where conflicts of interest would or would not exist. If an Investigator is uncertain as to which category applies to a given relationship or activity, then he or she should disclose that relationship or activity to the Conflict of Interest Committee for review and a determination.

CLASS A: Relationships or activities that are not allowed.

Examples of CLASS A:

- a. Investigations involving a known Conflict of Interest and human subjects who may be at risk from the procedures used; or
- b. Any Investigator making clinical referrals to a Business in which the Investigator, a member of his or her Family, or an Associated Entity of the Investigator has a Significant Financial Interest.

CLASS B: Relationships or activities that are only permitted after full disclosure to, and review, and written approval by the Conflict of Interest Committee. The Conflict of Interest Committee's approval may be contingent on certain requirements being implemented, including but not limited to,

on-going review and oversight by the Committee.

Examples of CLASS B:

- a. Investigations involving a potential Conflict of Interest and human subjects who may be at risk from the procedures used;
- b. Any Investigator conducting research externally that would ordinarily be conducted within UNTHSC or an affiliate;
- c. Any Investigator assuming an Executive Position in a Business engaged in commercial or research activities;
- d. An Investigator receiving sponsored research through UNTHSC or gifts (whether in dollars or in kind) for research from a Business in which the Investigator, a member of his or her Family or an Associated Entity of the Investigator has a consulting agreement whereby a per hour or any other fee is received.
- e. A relationship or activity where an Investigator, his or her Family, or an Associated Entity of the Investigator possesses a material, decision-making or Significant Financial Interest in a commercial or professional activity or Business that has a potential impact on a proposed, awarded or ongoing UNTHSC research project involving the Investigator;
- f. Any Investigator, or his or her Family, or an Associated Entity of an Investigator possessing a Significant Financial Interest in: 1) a Business that competes with the services provided by UNTHSC, or 2) a clinic;
- g. Any Investigator taking administrative action within UNTHSC or any affiliate that is beneficial to a Business in which Investigator, Investigator's Family, or an Associated Entity of Investigator has a Significant Financial Interest;
- h. Any Investigator participating in research on a technology developed by a member of his or her Family or an Associated Entity of the Investigator;
- i. Any Investigator serving on the Board of Directors or any Advisory Board of a Business from which the Investigator or a member of his or her Family or an Associated Entity of the Investigator

- receives Sponsored Research support or with which UNTHSC has a contractual relationship;
- j. Any Investigator who assigns students, post-doctoral fellows or other trainees to projects sponsored by a Business in which the Investigator, a member of his or her Family, or an Associated Entity of the Investigator has a Financial Interest; or
 - k. Any Investigator who applies for Public Health Service and/or National Science Foundation funding for research and the Investigator, or a member of his or her Family, or an Associated Entity of the Investigator have a Significant Financial Interest that could directly affect the design, conduct or reporting of the federally funded research.

CLASS C: Relationships or activities that are normally allowable because they involve minimal financial interests, are generally accepted practices and/or are unrelated to institutional activities. These situations do not require disclosure to the Conflict of Interest Committee, unless a known conflict of interest exists.

An example of CLASS C:

- a. Any Investigator participating in the review, assessment or consideration by a committee of a governmental agency, such as a study session, or a private sponsor of Clinical Research;

SELF-DISCLOSURE OF SITUATIONS INVOLVING POTENTIAL CONFLICTS OF INTEREST

Faculty

In order to help in the identification of potential conflicts of interest, all Investigators involved in research shall be required to submit a "Statement of Interest Form" (hereinafter referred to as "Statement") to accompany any research proposal of the Investigator, regardless of support. This Statement shall be submitted to the Chair of the Investigator's department who must review it, sign it and submit it to the Research Office. Failure to submit the Statement or submission of an incomplete Statement may result in delay of the submission of grant applications.

Initial review of the Statement will be conducted by the Research Office. Individual Investigators will be notified of any additional information that is necessary for the Statements. Information necessary to complete the process shall be submitted within thirty days from the date of notice of incompleteness. Regardless of review by the Research Office, it remains the responsibility of the individual Investigator to fully disclose all information on the Statement.

Fully completed Statements will be divided into two categories:

- a. Statements that do not involve a Class A or Class B situation; a Significant Financial Interest or other potential conflicts of interest will require no further review. Records will be maintained, identifiable to any grant awarded to the Investigator, showing that review has taken place and no further action is needed by the Investigator, unless a factual change occurs. If required by a granting agency, notice of such will be forwarded to the agency in accordance with the agency's policy.
- b. Statements that involve a Class A or Class B situation, a Significant Financial Interest and/or other potential conflicts of interest will require further review. Statements including Category A situations will not be approved. Statements including Category B situations will only be approved after full disclosure to, review and written approval by the Conflict of Interest Committee

THE CONFLICT OF INTEREST COMMITTEE

President

The President shall annually appoint a standing Conflict of Interest Committee which shall consist of not less than three members and two alternate members. Members shall serve three-year terms, which will be staggered. Committee members shall elect a Chair annually; the President shall resolve any unbreakable ties in voting. Should any member fail to complete his/her term the President shall appoint a replacement for the remainder of that member's term. The President may remove a Committee member at any time for failure to perform his/her 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 Chancellor shall resolve any conflict of interest issues involving the President of UNTHSC.

The Conflict of Interest Committee shall be responsible for:

- a. soliciting, reviewing, and maintaining records of the potential Conflict of Interest information required by this Policy;
- b. obtaining additional information from Investigators and other sources as necessary to make informed judgments and decisions;
- c. taking appropriate action to identify, investigate, manage, reduce, resolve and/or eliminate actual and potential conflicts of interest in accordance with this Policy. Such resolution may include, but is not limited to, the public disclosure of a Significant Financial Interest, monitoring of research by independent reviewers, modification of research plans, disqualification from participation in research including, but not limited to, Public Health Service and/or National Science Foundation funded research, divestiture of the Significant Financial Interest, and/or requiring the severance of relationships and/or activities that have created the potential conflict of interest;
- d. after full review of a matter, issuing a written determination to the Investigator;
- e. notifying the President of significant potential Conflicts of Interest that have been reviewed by the Conflict of Interest Committee;
- f. reporting the results of all determinations and all actions taken to the Provost and Executive Vice President For Research for communication to the appropriate agencies; and
- g. maintaining confidentiality, to the extent permitted by law, on all disclosures and records of actions taken to manage potential conflicts of interests for at least three years beyond the termination or completion of the award or until resolution of any action by federal agency involving the records, whichever is longer, and making these records available for audit by authorized agencies.

RESPONSIBILITIES OF THE RESEARCH OFFICE

Vice President for
Research

The Research Office shall be responsible for:

- a. providing Investigators involved in research who are submitting research proposals with copies of the Conflict of Interest Policy and the Statement Interest Form;
- b. receiving, reviewing and maintaining Statement of Interest Forms from Investigators and forwarding applicable Forms to the Conflict of Interest Committee;
- c. certifying to the awarding component of a federal agency the determination of the Conflict of Interest Committee regarding the existence of potential conflicts of interest and the management thereof prior to submission of the grant/contract application. Prior to the submission of a grant application, the Investigator involved in the research and Vice President for Research or designee must both sign the specified certifications regarding Significant Financial Interests, in compliance with this Policy with its regulatory basis;
- d. notifying the awarding component of the federal agency of the identification and management, reduction, or elimination of any Significant Financial Interest that originates or becomes known to UNTHSC after an award has been made and within sixty days of its report to the Conflict of Interest Committee;
- e. maintaining confidentiality, to the extent permitted by law, of all disclosures and records of actions taken to manage potential conflicts of interest for at least three years beyond the termination or completion of the award or until resolution of any action by a federal agency involving the records, whichever is longer, and make these records available for audit by authorized agencies;
- f. records will be maintained, identifiable to any grant awarding to the Investigator, showing that review has taken place; a process for management of the potential conflict has been made. If required by a granting agency, notice of such will be forwarded in accordance with the granting agency policy.

RESPONSIBILITIES AND RIGHTS OF APPEAL OF INVESTIGATORS INVOLVED IN RESEARCH

Faculty

UNTHSC Investigators involved in research shall be responsible for:

- a. reading, understanding and following this Policy;
- b. disclosing financial and commitment interests to the UNTHSC Research Office by completing, signing, and submitting the Statement of Interest Form on or before a specified date or before submission of the grant/contract application;
- c. ensuring that funded research carried out through subgrantees, contractors or collaborators provide that these entities' Investigators comply with the UNTHSC's Conflict of Interest Policy or that the entity provide assurance of compliance with all federal regulations and state law;
- d. updating the Statement of Interest Form with the Research Office as changes occur, so that the Statement on file is current and accurate at all times when an award is pending or in force;
- e. Prior to submission of a grant application, the Investigator involved in the research and Vice President for Research or designee must both sign the specified certifications regarding Financial Interests, in compliance with this Policy and with its regulatory basis;
- f. making the following certification to UNTHSC and to the granting agency prior to the submission of the grant/contract application:

"I have read and understand the University of North Texas Health Science Center at Fort Worth Conflict of Interest Policy, Ethics Policy, and Outside Employment Policy, and I have disclosed all potential financial and commitment interests as required by all UNTHSC policies, including those policies. I will comply with provisions of UNTHSC policies to report changes in my Financial Interests and will comply with conditions or restrictions imposed by UNTHSC to manage, reduce or eliminate actual or potential conflicts of interest."

In the event of disagreement with the findings and/or decisions of the Provost and Executive Vice President or designee, the Investigator may appeal those findings/decisions to the UNTHSC President. In such cases, the President shall review all of the materials relating to the action in question, shall discuss the findings/decisions with the Investigator and the Provost and Executive Vice President or designee, and shall make a final decision as to the action. All decisions of the UNTHSC President of an appeal under this Policy are final. President

CONSULTING AGREEMENTS INVOLVING EMPLOYEES

Faculty and staff members involved in research 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 see to it 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 responsibilities of the faculty or staff member to UNTHSC. Faculty

Rights in inventions within the scope of the faculty and staff member responsibilities to UNTHSC developed using the 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 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.”

References and Cross-references.

Chapter 572 of the Texas Government Code

Policies 05.505 and 05.506 of UNTHSC's Personnel and Procedures Manual

Forms and Tools. (optional)

Statement of Interest Form

Potential Conflict of Interest Questionnaire

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