



10.1.12 Institutional Conflict of Interest Policy

Chapter 10 - Ethics, Standards of Conduct, and Relationships with External Entities	Original Effective Date: November 2005
Section: 10.1 Ethics, Standards of Conduct and Relationships with External Entities	Date Last Reviewed: November 2015
Responsible Entity: Vice President for Research	Date Last Revised: November 2015

I. Purpose

To establish the best practices and ensure compliance with the law to protect the credibility and reputation of UT Health San Antonio by providing a framework to address conflicts of interest.

II. Scope

This policy applies to all faculty, staff, students, residents, healthcare providers, researchers, contractors, or any other individual (collectively, Workforce Member, including employees and non-employees).

III. Policy

A. Overview

As a recipient of public funds, the UT Health San Antonio (UTHSA) has a responsibility to ensure that all its research and business development activities are in the best interest of the community. This policy provides appropriate institutional safeguards to sustain a climate in which sponsored projects, dedicated gifts, research, scholarship, technology transfer and business development are carried out responsibly, and in so doing foster an atmosphere of openness and integrity. Moreover, the institution has a responsibility to ensure that no one should unfairly benefit from the public trust or reputation of UTHSA. Finally, the welfare of human participants in research and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations.

B. Policy

1. Institutional Conflicts of Interest may involve the financial interests of an Institutional Official or may involve the financial interests of the institution itself. Each institutional financial interest that presents a potential for Institutional Conflicts of Interest, whether real or perceived, must be fully disclosed to the

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University's Conflict of Interest Committee. The Office of the Vice President for Research is responsible for administration and support of the Conflict of Interest Committee.

2. Disclosures of financial interests of an Institutional Official are addressed in the Institutional Handbook of Operating Policies (HOP) Policy [10.1.6, Conflicts of Interest in Research and Disclosure](#) and Policy [10.1.9, Conflict of Interest, Conflict of Commitment and Outside Activities](#). This policy will address the financial interests of the institution.
3. The conflict of interest must be properly identified and managed or eliminated before any contract, sponsored project, dedicated gift, or transaction is executed; any contractual relationship is initiated; or any action is taken that might be influenced or appear to be influenced by the conflict of interest.

C. Guiding Principles

1. Institutional Conflict of Interests must not be allowed to undermine the objectivity of, or missions or activities in research, teaching, clinical care, or their administration at the UTHSA.
2. Relationships between UTHSA and public and private entities are encouraged, play an important role in the achievement of UTHSA's missions, and can be mutually beneficial; however, the UTHSA must disclose and manage any relationship that compromises or appears to compromise its integrity or missions.
3. A central principle is that conflicts of interest of UTHSA or one of its Institutional Officials should be avoided or eliminated where possible. However, if compelling circumstances justify an activity with inherent conflicts of interest, a comprehensive management plan must be developed, approved, implemented, and monitored. The purpose of each management plan is to minimize the likelihood that the institutional conflict will pose risks of undue influence on decisions involving UTHSA's Institutional Officials, primary interests, or key missions.

D. General Guidelines for Controlling or Managing Conflicts

Primary methods for conflict resolution could include (but certainly are not limited to):

1. Eliminating the conflict by referring the research to another study site that has no institutional conflicts at work or divesting or sequestering the conflicting financial interest.
2. Requiring that institutional investments posing a conflict of interest in a research study be "frozen" for a designated period after the termination of the study, with the University allowed neither to sell nor transfer those interests until a time certain, thus providing for a forced attenuation of the research study and its results from the institutional interest.

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3. Disclosing the conflict to sponsors, research subjects, and/or publications and journals.
4. Providing independent checks or monitors on the research approval and oversight process, such as an independent review and monitoring of the Institutional Review Board (IRB) review and continuing review processes.
5. Providing independent monitoring of the subject recruitment and/or informed consent processes.
6. Limiting subject recruitment so that it does not target, or even allow, participation by UTHSA staff and dependents.
7. Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting.
8. Arranging for independent review of all adverse events, including review of subject records on a comprehensive, periodic, or sampled basis to assure that reports of adverse events have been timely and properly made.
9. Requiring revisions to the panel of investigators or the research staff, to lessen any influence that the institutional interest might have over the course and reporting of the research; and/or adopting procedures for the updating of information relating to the institutional conflict, if it appears that the conflict might change in any appreciable way over the course of a research study.
10. Approval of a management plan for institutional officials having significant financial interests in organizations sponsoring research at UTHSA by an appropriate Vice President who does not, directly or indirectly, have the individual holding a significant financial interest in the sponsoring organization reporting to that office. Upon recommendation by the Committee, this Vice President should determine whether the significant financial interests in an investigational product or in a sponsor of human subjects' research may be managed effectively or should be eliminated. If the Vice President finds that an official should be permitted to hold a significant financial interest in an investigational product or commercial research sponsor even though the official will not be formally recused from research-related responsibilities, this information shall be communicated to the IRB.
11. Review of financial interests of IRB members
 - a. The Committee should apply a presumption against significant individual financial interests in an investigational product or a commercial sponsor of the institution's human subjects' research.
 - b. IRB members are required by federal regulation to recuse themselves from voting upon or participating in any deliberations concerning protocols in which they have conflicting interests.
 - c. UTHSA requires that the IRB Chair polls the IRB about potentially conflicting financial interests prior to the start of each meeting and to document member's

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responses in the meeting minutes. When possible, the Vice President for Research will provide the IRB Chair with a list of the research sponsors in which one or more IRB members hold a significant financial interest, to ensure that recusal occurs when necessary.

- E. The Committee will apply the following principles to determine whether a financially interested individual or the institution has demonstrated compelling circumstances that justify allowing that individual or UTHSA to conduct human subjects' research.
1. **Magnitude of Risk:** The institution should determine the nature and degree of scrutiny required for any of these relationships or interests by assessing the potential for conflict of interest and weighing the magnitude of any risk to human subjects.
 2. **Rebuttable Presumption:** The rebuttable presumption against financial interests in human subjects' research may be rebutted when the circumstances are compelling, and the Committee has approved an effective conflict management plan.
 3. **Evaluation Criteria:** When considering a request by a financially interested individual to conduct human subjects research, the circumstances that the Committee should evaluate include:
 - a. the nature of the research;
 - b. the magnitude of the interest and the degree to which it is related to the research;
 - c. the extent to which the interest could be directly and substantially affected by the research;
 - d. the degree of risk to the human subjects involved that is inherent in the research protocol;
 - e. the extent to which the interest is amenable to effective oversight and management; and,
 - f. whether the individual is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual.
 4. **Compelling circumstances to allow the institutional conflict depend upon:**
 - a. the nature of the science;
 - b. the nature of the interest;
 - c. how closely the interest is related to the research;
 - d. the degree of risk that the research poses to human subjects;
 - e. the degree to which the interest may be affected by the research; and,
 - f. whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience

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and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved. (Even when found uniquely qualified, conflicts should be avoided whenever possible and managed closely if permitted.)

5. External Monitoring of Single/Primary Site Trials: Serving as the sole or primary performance site might be justified under compelling circumstances (e.g., when the research is an early- stage or feasibility trial and the expertise of institutional investigators is essential to the research). In such a case, however, the Committee should approve the circumstances, and if advisable, the research should be subject to monitoring by an oversight body with external members (e.g., a data and safety monitoring board).
6. External IRB Review: When the Committee has determined that compelling circumstances exist, the institution should consider the desirability of contracting with an external IRB to provide a second level of review and oversight.
7. Other Financial Relationships That May Warrant Close Scrutiny: When an investigator, research administrator, or institutional official with research oversight authority participates materially in a procurement or purchasing decision involving major purchases from, or non-routine supply contracts with, a commercial entity that sponsors human subjects research at the institution; or,

When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of human subject's research.

F. Management Plans

Should it become necessary to develop an Institutional Conflict of Interest Plan, it will be submitted for approval to the University of Texas System Office of General Counsel and the Executive Vice Chancellor for Health Affairs. Prior to submission to the Executive Vice Chancellor for Health Affairs, the President, Vice President for Research and other Institutional Officials (as applicable) will receive a copy of the Committee's recommendations and will have the opportunity to provide comments.

G. Other Complementary Policies

UTHSA, The University of Texas System, and the State of Texas have promulgated other policies and regulations that relate to this policy including, but not limited to the following:

1. HOP Policy [10.1.2 Code of Ethics and Standards of Conduct](#)
2. HOP Policy [10.1.3 Personal use of University Resources, Equipment, and Assets](#)
3. HOP Policy [10.1.4 Giving and Receiving Benefits](#)
4. HOP Policy [10.1.5 Political Activities](#)

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5. HOP Policy [10.1.6 Conflicts of Interest in Research and Disclosure](#)
6. HOP Policy [10.1.9 Conflict of Interest, Conflict of Commitment and Outside Activities](#)
7. [UTS 134](#), Code of Ethics for Financial Officers and Employees
8. Regents' [Rules 30103](#), Standards of Conduct
9. Regents' [Rules 30104](#), Conflict of Interest, Conflict of Commitment, and Outside Activities
10. Texas Government Code, [Chapter 572](#), Personal Financial Disclosure, Standards of Conduct, and Conflict of Interest

IV. Definitions

When used in this document, the following words have the meaning set forth below unless a different meaning is required by context.

Institutions Conflict of Interest (ICOI) – Institutional Conflicts of Interest arise when UTHSA's financial interests or those of its Institutional Officials pose risks of undue influence on decisions involving UTHSA's primary interests or missions (e.g., research, teaching, and clinical care or administration of these missions).

Institutional Official – Any employee or other individual with the authority to make decisions to commit resources of UTHSA.

Significant Outside Financial Interest of UTHSA – Significant Outside Financial Interests of UTHSA can occur when the following is received:

1. Cumulative gifts from any person, business, or entity within the past ten years of:
 - a. \$1,000,000 or more to the university; or
 - b. \$100,000 or more to an institutional department; or
 - c. \$5,000 or more to an individual to conduct "research."
2. Payments from a person, business, or entity for the licensing of intellectual property that, on aggregate, exceed \$250,000 per calendar year.
3. Equity and ownership interests in entities held by UTHSA, including equity and ownership resulting from technology transfer activities where:
 - a. such equity or ownership interest has a value of more than one million dollars in the case of a publicly traded entity, or
 - b. any ownership interest in a non-publicly traded entity.

V. Related References

There are no related documents associated with this Policy.

VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
11/2005	Policy Origination		
11/2015	Policy Revision		