

Institutional Conflicts of Interest

Policy Number: 221

<p>Subject: Financial interests of the university and of the university's institutional officials acting on behalf of the institution that pose or may pose risks of undue influence on decisions that affect the research, education, clinical care, business transactions, or other activities of the institution.</p> <p>Scope: This policy applies to the President, Vice Presidents, Executive Vice Presidents, Associate Vice Presidents and Assistant Vice Presidents; Deans, Vice Deans, Associate and Assistant Deans; Department Chairs; directors of institutes and directors of organized business or research units (e.g., procurement, sponsored projects, compliance, asset management, business affairs); all licensing, marketing and commercialization professionals in the institution's technology commercialization office who have the authority to bind the institution; and any other person designated by the President as an institutional official for the purposes of this policy.</p> <p>Date Reviewed: July 2016</p>	<p>Responsible Office: Office of the Executive Vice-President & Chief Academic Officer</p> <p>Responsible Executive: Executive Vice-President & Chief Academic Officer</p>
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I. POLICY AND GENERAL STATEMENT

The University of Texas Health Science Center at Houston ("university") has an obligation to conduct its activities with utmost integrity. At times, the university and its employees must balance competing interests. Academic-industry relationships are important to advancing scientific frontiers and essential to enabling commercial development of academic and research discoveries for the benefit of the public. These relationships may lead to financial benefit to

institutions. Institutional conflicts of interest ("Institutional COI") may involve financial interests of institutional officials or the university itself. Such conflicts of interests should be properly identified and managed so they do not compromise or appear to compromise the primary mission of the university in patient care, research and education.

This policy is intended to protect the credibility and reputation of the university, UT System, and employees of the university by providing a transparent system of approval, disclosure, and documentation of financial interests of university officials and the university that may raise concerns about conflicts of interest.

Outside financial interests of the institution or institutional officials must not be allowed to undermine the objectivity of, or missions or activities in, research, education, clinical care, or their administration at the university. The university must disclose and manage any relationship that compromises or appears to compromise its integrity or missions. A central principle is that conflicts of interests of the university or its officials should be avoided or eliminated where possible. However, if compelling circumstances justify an activity with inherent conflicts of interests, a comprehensive Management Plan ("Plan") must be developed, approved, implemented and monitored.

II. DEFINITIONS

Family member:

- A spouse;
- a dependent child or stepchild or other dependent (for purposes of determining federal income tax liability during the period covered by the disclosure statement); and
- a related or non-related, unmarried adult who resides in the same household as the individual and with whom the individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

Institutional Conflict of Interest: An Institutional COI describes a situation in which the financial interests of the university or of a Level I or Level II institutional official (see below), acting within his or her authority on behalf of the institution, poses or may pose a risk of undue influence on decisions that affect the research, education, clinical care, business transactions, or other activities of the institution.

Institutional Officials: Any employee or other personnel with the authority to make decisions to commit resources of the institution.

Level I Institutional Official: The President of the university.

Level II Institutional Officials: Executive Vice Presidents, Vice Presidents, Associate Vice Presidents and Assistant Vice Presidents; Deans, Vice Deans, Associate and Assistant Deans; Department Chairs and Directors of institutes or centers; Directors of organized business or research units (e.g., procurement, sponsored projects, compliance, asset management, business affairs); all licensing, marketing and commercialization professionals in the institution's technology commercialization office who have the authority to bind the institution; and any other person designated by the President as an institutional official for the purposes of this policy.

Significant Outside Financial Interests of the University: Significant outside financial interests of the university occur, but are not limited to, circumstances where the institution receives:

- a. Cumulative gifts from any person, business or entity within the past 10 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.
- b. Payments from a person, business or entity for the licensing of intellectual property that, in aggregate, exceed \$250,000 per calendar year.
- c. Equity or ownership interests in entities held by the institution, including equity and ownership interest resulting from institutional technology transfer activities, where:
 1. Such equity or ownership interest has a value of more than \$1,000,000 in the case of a publicly traded entity, or
 2. The institution has any ownership interest in a non-publicly traded entity, and the capitalization of the entity exceeds \$1,000,000.

Significant Outside Financial Interests of an Institutional Official: Significant outside financial interests of an institutional official occur, but are not limited to circumstances where the institutional official has the following:

- a. Substantial interest in a business:
 1. A controlling interest;
 2. Ownership of more than 1% of the voting interest;
 3. Ownership of more than \$5,000 of the fair market value;
 4. A direct or indirect participating interest by shares, stock or otherwise, regardless of whether voting rights are included, in more than 1% of the profits, proceeds or capital gains; or
 5. Service as an officer.
- b. Gifts over \$250, in aggregate within a 12 month period, to the institutional official or his/her immediate family members. Does not include gifts received from: a parent, child, sibling, grandparent, or grandchild, the spouse of the employee and spouse of anyone described above;
- c. Outside activities that may reasonably appear to impact or affect the university's activities or missions; or otherwise appear to create an institutional conflict of interest; and
- d. Any activity of an institutional official's immediate family member(s) or any substantial interests of immediate family members in business entities that may reasonably impact or affect, or appear to impact or affect, the institution's activities or missions.

III. PROCEDURE

A. Disclosure of Financial Interests

Disclosures of financial interests of institutional officials are addressed in HOOP 20, Conflict of Interest, Conflict of Commitment and Outside Activities. Financial interests of the university itself will be obtained by the Conflict of Interest Office annually from:

1. the Office of Technology Management: Licensing revenues (royalties and/or equity) from technology commercialization or technology transfer activities and ownership interests held by the university;
2. the Development Office: gifts/grants from donors received by the institution;
3. Sponsored Projects Administration: Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants where there is an Institutional COI; and
4. any other appropriate sources.

B. Institutional Conflicts of Interest Committee

The Office of the Executive Vice President & Chief Academic Officer shall maintain an Institutional Conflicts of Interest Committee (ICOIC) established by the Executive Compliance Committee (ECC). The Committee shall be appointed and charged and operate according to bylaws created by the ECC.

The purpose of the ICOIC is to provide advice, guidance and recommendations to the President, the Chief Compliance Officer (CCO), the Executive Compliance Committee (ECC), the Executive Vice President & Chief Academic Officer ("EVP/CAO"), the Chief Operating/Chief Financial Officer (COO/CFO), and The University of Texas System Executive Vice Chancellor for Health Affairs (EVC) regarding real, perceived, and potential conflicts of interest of the University and its officials. For purposes of this policy, specific responsibilities of the ICOIC include the following:

- a. Establishing mechanisms to identify real, perceived, and potential conflicts of interest due to the university's financial interests and those of its institutional officials ("Institutional COI") that pose risks of undue influence on the University's decisions, functions and actions related to its mission; and
- b. Reviewing the financial interests of the university, its institutional officials, and other employees to identify real, perceived, or potential institutional and individual conflicts of interest (HOOP 20, Conflict of Interest, Conflict of Commitment and Outside Activities).
 1. If the Committee believes a conflict can be managed to prevent undue influence on the university's decisions, functions, or actions, or those of an employee(s), it shall recommend a Plan that must be approved by the EVP/CAO and the COO/CFO. Any Plans involving the EVP/CAO or the COO/CFO must be approved by the President.
 2. If the Committee believes a conflict cannot be eliminated or managed so as to prevent undue influence on the university's decisions, functions, and actions, or those of an employee(s), it shall recommend to the ECC actions to remove the conflict. If the ECC concurs, it will forward the recommendation to the President for a final decision and implementation.
- c. Providing additional information, guidance, and recommendations to the President, CCO, ECC, EVP/CAO, COO/CFO, and EVC upon request.

Any member of the ICOIC who has a financial interest in or serves as a paid consultant for an entity shall not participate in the review of the Institutional COI issues related to that entity under this policy.

C. Management of Institutional Conflicts of Interest

Institutional COIs arise when an institution's financial interests or those of its institutional officials pose risks of undue influence on decisions involving the institutions primary interests or missions (e.g., research, teaching, and clinical care) or administration of these missions. A central principle is that conflicts of interest of the institution or of an institutional official(s) should be avoided or eliminated where possible. However, if compelling circumstances justify an activity with inherent conflicts of interest, a comprehensive Plan must be developed approved, implemented, and monitored. The purpose of each Plan is to minimize the likelihood that the Institutional COI will pose risks of undue influence on decisions involving institutional officials, primary interests, or key missions.

Institutional COIs involving the university's financial interests and those of its Level II institutional officials will be managed by the ECC upon the recommendation of the ICOIC. The ICOIC will identify real, perceived, or potential conflicts of interest of the university and its Level II institutional officials based upon review of their required financial disclosures, their approved outside activities and any associated financial relationships, and any other disclosures or reports required by this policy. Based upon its review of these materials, the ICOIC will recommend elimination or management of the conflict.

When an Institutional COI is related to proposed or ongoing research, the ICOIC will work with the Research Conflict of Interest (RCOI) Committee and the Institutional Review Board (IRB) to manage the Institutional COI.

Some of the possible management strategies include, but are not limited to:

1. Eliminate the financial interest (e.g., divestiture) or reduction to a level below the minimum threshold;
2. Recuse an institutional official from decision making or participation in an activity that would directly or indirectly involve the person's financial interest;
3. Place the conflict-causing economic interests (e.g., stocks, options, bonds) in a blind or double-blind trust;
4. Require oversight of decision-making or participation in an activity by an independent third party;
5. Recuse an institutional official from participation in negotiations involving a financial transaction or licensing agreement between the affected institution and the relevant entity;
6. Recuse an institutional official from approval of extramural time off for any individual related to relevant entity;
7. Alter the reporting structure when a Level II institutional official having a financial interest with a specific entity directly supervises someone who also has a relationship with the same entity (including, but not limited, to sponsored research); and/or
8. Obtain outside IRB review or independent monitoring for human subjects research that is related to the university's financial interest.

1. Level I Institutional Official

The EVC, or designee, holds the authority to review compelling circumstances regarding any conflicts and to identify, create and approve plans for managing, reducing, or eliminating Institutional COIs involving the President. The EVC will make a final decision and issue directives to the ICOIC for handling, processing, and oversight of compliance as needed, as well as any subsequent information or reports he/she requests.

2. Level II Institutional Official

If management is recommended, the ICOIC will develop a Plan after consultation with the Level II Institutional Official. Plans must be initially approved by the EVP/CAO and COO/CFO. After approval, the EVP/CAO will forward the recommended Plan to the President. The President, or designee, holds the final authority within the institution to review compelling circumstances regarding conflicts and to approve Plans for managing, reducing or eliminating real, potential, or perceived conflicts of interest involving Level II Institutional Officials. At his/her discretion, the President may consult with the Level II Institutional Official and/or others prior to making a final institutional-level decision. Plans approved by the President will be submitted to the UT System Office of General Counsel (OGC) and the EVC for final review and approval.

3. Institutional Interests

For instances involving the university's financial interests, the authority to reject, modify or approve Plans lies with the EVC. The ICOIC shall identify potential conflicts of interest involving the university's financial interests and shall review, recommend elimination, and/or management of the institutional conflicts of interest, and will inform the President of its recommendations and provide an opportunity for his/her comments. The Committee shall forward its recommendations to the OGC and EVC for final review and approval.

The ICOIC shall review Plans annually to determine if the Institutional COI persists, document compliance with previous Plans and assess the need for reissuing or modifying the Plan.

The ICOIC is also responsible for periodically reviewing conflict of interest policies and procedures and recommending changes as required.

D. Reporting

For instances where a Plan is developed, the EVP/CAO Conflicts of Interest Office will submit it to OGC and the EVC for review and approval.

E. Non-Compliance

Failure to comply with any portion of this policy, applicable federal regulations, state laws, rules and regulations of The University of Texas Board of Regents, UT System policies, university policies, and/or the terms of an approved Plan may result in the total withdrawal of, or limitations to, the university's approval of institutional officials' outside activities. Further, such failure may result in disciplinary action, up to and including termination of employment. Civil and criminal penalties may also apply under certain circumstances.

Employees should report any suspected noncompliance to their immediate supervisors or to the Office of the Executive Vice President & Chief Academic Officer. Employees may also anonymously report suspected violations to the toll-free Compliance Hotline at 1-888-472-9868. In accordance with HOOP, 108 Protection from Retaliation, retaliation for a good-faith report of suspected violations will not be tolerated. Detailed information on reporting possible violations may be found in the university's Standards of Conduct Guide.

F. Training

All employees are required to undergo mandatory compliance training, which includes training on conflicts of interest. For further explanation and guidance regarding this policy, refer to the Conflicts of Interest Guidelines or to the Standards of Conduct Guide or contact the Office of Executive Vice President & Chief Academic Officer.

IV. CONTACTS

Contact	Telephone	Email/Web Address
Office of the Executive Vice President & Chief Academic Officer - Conflict of Interest Office	713-500-3214	https://inside.uth.edu/evpara/coi/index.htm Research_COI@uth.tmc.edu