

UT SOUTHWESTERN POLICY HANDBOOK

ETH-304 INSTITUTIONAL CONFLICTS OF INTEREST

CHAPTER 3: ETHICS, COMPLIANCE, AND STANDARDS OF BEHAVIOR

CONTENTS

Policy Rationale and Text
Scope
Procedures
Responsibilities
Definitions
Related Statutes
Contacts/For Further Information
Policy History

ADMINISTRATIVE INFORMATION

Responsible Office: Office of the President
Executive Sponsor: President
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Contact: policyoffice@utsouthwestern.edu

POLICY RATIONALE AND TEXT

The mission of UT Southwestern is to improve healthcare in our community, Texas, our nation, and the world through innovation and education. In pursuing this mission, UT Southwestern, as a state agency and university, has a responsibility to the people of Texas to conduct its activities with the utmost integrity.

UT Southwestern and its institutional officials often must balance competing interests in advancing the University's mission. University-industry relationships are important to advancing scientific frontiers and essential to enabling the commercial development of academic discoveries for the benefit of the public. In addition, UT Southwestern engages in relationships with a variety of individuals and outside entities that may lead to financial benefit for the institution in many forms, including royalty payments, other payments and equity from licensing intellectual property, sponsored educational and research agreements, and major philanthropic gifts. Such relationships with individuals and outside entities are generally part of legitimate educational, research, and business activities.

An institutional conflict of interest ("ICOI") may exist when the financial interests of UT Southwestern or of an institutional official, acting within his or her official capacity on behalf of the institution, may compromise or bias, or appear to compromise or bias, the research, education, clinical care, business transactions, investments, or other activities of the institution. This policy is not intended to prohibit or discourage university-industry relationships, or preclude UT Southwestern from creating, transferring, or benefiting from its own technology in fulfilling its mission. Nor should this policy prevent UT Southwestern from accepting philanthropy or grants for research, education, clinical programs, or other appropriate work. Relationships between UT Southwestern and outside entities are encouraged, play an important role for the institution in achieving its missions, and can be mutually beneficial. Instead, this policy is intended to establish a process for identifying, disclosing and examining ICOIs to manage them, as much as possible, to ensure that institutional decisions regarding research, education, clinical care, business transactions, investments, and other activities are not compromised or biased by financial interests of UT Southwestern or its institutional officials.

UT Southwestern institutional officials are in special positions of authority to influence the University's academic mission, strategic vision, administrative priorities, and business decisions, and so must be particularly careful not to allow any ICOI to undermine the objectivity of, or missions or activities in, research, education, clinical care, or their administration of the institution. At all times, UT Southwestern institutional officials must treat their responsibilities to UT Southwestern as their primary professional obligations, act in a manner consistent with their assigned institutional responsibilities, and exercise reasonable care to avoid situations that may create a conflict of interest or conflict of commitment with their institutional responsibilities or the appearance of a conflict. Institutional officials must be alert at all times to areas of conflict that may be novel or unusual or particular to their functions.

No institutional official may materially participate in any decision-making involving purchasing, procurement, or contracting for products or services (including, without limitation, products or services used in the delivery of patient care, course materials or other educational tools, or maintenance or construction of University equipment or facilities) under circumstances in which a reasonable person could infer that the decision-making could have been influenced by the desire for or expectation of direct or indirect personal financial gain. In instances where the institutional official's expertise is necessary in evaluating the transaction, the official's financial interest must be disclosed to those responsible for decision-making in the transaction so as to manage or mitigate the potential institutional conflict of interest.

Institutional officials shall not offer, solicit, or accept any gifts or other benefits in exchange for a decision, opinion, recommendation, vote, or other exercise of official discretion. In addition, institutional officials who exercise discretion in connection with contracts, purchases, payments, claims, or other pecuniary transactions shall not offer, solicit, or accept any gifts or other benefits from an individual or outside entity the institutional official knows is interested in or likely to become interested in any contract, purchase, payment, claim, or transaction involving the exercise of the institutional official's discretion. This standard applies even if the individual or outside entity does not ask for anything in exchange for the gift or benefit.

UT Southwestern must balance its relationship with external entities and individuals which may lead to financial benefit for the institution with its overarching institutional mission. Relationships that may financially benefit the institution must not compromise, or appear to compromise, the integrity of the institution's mission and research activities. It is the duty of UT Southwestern to ensure that institutional decisions regarding research, education, clinical care, business transactions, investments, and other activities are not compromised or biased by financial interests of UT Southwestern.

Subject to the requirements of this policy, UT Southwestern may accept gifts from outside entities that act as vendors for the institution or sponsor research (including human-subjects research) at the institution. All solicitation, acceptance, and processing of gifts must be coordinated through the Office of Development and conducted according to [FIM-601 Gifts - Solicitation, Acceptance, Processing, and Acknowledgement](#).

Because UT Southwestern's academic breadth and business activities are diverse and complex, it is not possible to describe every possible ICOI that may arise. Institutional officials who have questions about how this policy applies to a particular situation should seek advice from the Conflict of Interest Office.

This policy applies in addition to, and not instead of, general UT Southwestern or University of Texas System ("UT System") policies, such as policies on individual conflicts of interest and commitment, as well as other policies or statutes governing disclosure of activities and financial interests. If a specific law, regulation, or policy provides different requirements than this policy, the more stringent requirement applies.

SCOPE

This policy applies to all UT Southwestern employees.

PROCEDURES

ICOI Committee and COI Office

1. The President or designee shall appoint an ICOI Committee responsible for identifying and reviewing ICOI issues, developing management plans for potential ICOIs, monitoring compliance with management plans, and any other such tasks as assigned by the President.
2. The ICOI Committee will ordinarily consist of an odd number of members serving staggered four-year terms and it will be comprised of individuals with sufficient independence, expertise, and seniority. The ICOI Committee must include a minimum of seven members; at least one member from the Dallas-Fort Worth area with no affiliation with UT Southwestern; at least three senior faculty members from clinical and basic science departments, and the sitting chair of the COI Committee.
3. In circumstances where more than seven members comprise the ICOI committee, the minimum ratio of faculty to non-faculty members must remain as consistent as practicable with the 3:7 standard. Faculty members must be chosen by the president from a larger list of eligible faculty members created by the Faculty Council. This list must contain at least twice the number of faculty members as the final number to be selected by the president. Emeriti faculty shall be eligible to serve. The President (or designee) shall appoint the chair of the ICOI Committee.
4. The ICOI Committee shall meet as necessary to review ICOI issues, and maintain a record of its deliberations and actions. A quorum will consist of one more than half of the voting committee members, at least one of whom must be a member with no affiliation with the University. A representative of the Office of the Vice President for Legal Affairs shall attend meetings and serve as legal advisor to the ICOI Committee.
5. In relation to a specific matter before it, the ICOI Committee may invite a member of the University community with special expertise not otherwise available to the Committee to serve as a non-voting *ad hoc* member. At its discretion, the ICOI Committee may appoint non-voting, *ex-officio* members for renewable one-year terms.
6. The Conflict of Interest (COI) Office shall assist the ICOI Committee in administering and enforcing this policy. To identify potential ICOIs, the COI Office will gather information quarterly on interests described in this policy from the Office for Technology Development, the Development Office, pertinent units reporting to the Executive Vice President for Business Affairs and, to the extent relevant and when complete information is not available from those sources, from such other offices and individuals as may be designated by the President or the Chair of the ICOI Committee. On a quarterly basis and upon request, the COI Office will review individual Statements of Financial Interest and Outside Activities (“Statement”) of institutional officials and, in the event a potential ICOI is identified, refer the potential ICOI to the ICOI Committee for review.
7. Additional monitoring of, and assistance with, compliance with ICOI management plans will be performed by the COI Office.
8. No member of the ICOI Committee may participate in an initial or continuing review of a project in which that member may have a substantial interest with the business entity that is the subject of the review, except to provide information requested by the ICOI Committee. Members of the ICOI Committee are expected to disclose any financial interest which may be related to an initial or continuing review of a project.

Identification of Potential Institutional Conflicts of Interest

As a general guide, an ICOI may exist and a formal review by the ICOI Committee will be warranted where (i) UT Southwestern has a significant outside financial interest in an outside entity or (ii) any institutional official or covered family member has a

substantial interest in a business entity that itself has a financial interest in research, education, clinical care, business transactions, or other activities conducted by UT Southwestern.

1. UT Southwestern's receipt, possession, or ownership of a financial interest in an outside entity does not, standing alone, create an ICOI or warrant a formal review. It is only when UT Southwestern or an institutional official's financial interest in an outside entity is coupled with a current or reasonably foreseeable activity by that same outside entity in research, education, clinical care, business transactions or other activities conducted by or for UT Southwestern that review of the financial relationship is warranted. The following activities may warrant formal review if coupled with additional activities or relationships with UT Southwestern.
 - a. Licensing activities – When UT Southwestern licenses technology or other intellectual property, it may receive investment interests in a business entity as a result of the license, and/or royalties, milestone payments or other fees as compensation for the use of the intellectual property. UT Southwestern may also receive investment interests as part of a co-investment in a business entity by UT Southwestern. An ICOI may be created if an investigator undertakes to conduct externally funded research on a drug, device, biologic, or other item on which the Board of Regents of the University of Texas System owns a patent or has filed a patent application, has licensed intellectual property, or receives or has received investments interests, royalties, or other licensing fees.
 - b. Governance/fiduciary roles – Through licensing activities or investment interests related to such activities, UT Southwestern may obtain the right to appoint an institutional official with broad administrative authority to serve with or without compensation in either a personal or representative capacity as an officer, director or scientific advisory board member of a sponsor of research conducted at or under the auspices of UT Southwestern.
 - c. Gifts to UT Southwestern – Before a gift is accepted either directly from an outside entity or through a supporting foundation, the following circumstances should be evaluated:
 - i. Whether a gift is of sufficient magnitude or impact that even when held in the general endowment for the benefit of the entire institution, it might affect or reasonably appear to affect oversight of operations within the institution.
 - ii. Whether a gift held for the express or limited benefit of a school, department, center, or other unit is of sufficient magnitude that it might affect or reasonably appear to affect the operations within the school, department, center, or other unit.
 - iii. Whether the terms and conditions of the gift are consistent with the institution's mission.
 - iv. Whether any institutional official who has the authority to affect or reasonably appear to affect the objectivity of, or missions or activities in, research, teaching, clinical care, or their administration at the institution also has been actively involved in solicitation of the gift, or in the management of the gift once received by UT Southwestern.

Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude or discourage UT Southwestern from accepting philanthropy directly from outside entities or through a supporting foundation in support of UT Southwestern's missions. Rather, this policy is intended to help UT Southwestern develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate any actual or reasonably apparent conflicts of interest that may result. The solicitation, acceptance and processing of gifts must be coordinated through the Office of Development according to existing UT Southwestern policies.

2. Substantial interests in business entities held by institutional officials or covered family members warrant formal review of potential ICOI when those interests could directly or significantly affect the proper discharge of the official's own

institutional responsibilities or when a reasonable person could infer that decision-making authority of another employee could be influenced by the institutional official. Examples include, without limitation:

- a. Purchasing or other business transactions – An ICOI can arise when an institutional official with a financial interest in an outside entity participates or seeks to participate materially in procurement, purchasing, or other business transactions (including, without limitation, transactions involving the delivery of patient care or the maintenance or construction of University equipment or facilities) involving the business entity.
- b. Educational and training activities – When an institutional official has a financial interest related to the selection of course materials or educational tools (including software, textbooks or reference books) being used in the delivery of educational or training activities at UT Southwestern, an ICOI may arise.
- c. Administrative decisions – An institutional official’s financial interests in an outside entity can bias or appear to bias decisions about faculty appointments or promotions, salary, assignment of office or laboratory space, or other administrative matters in favor of the outside entity’s interests.

Review and Management of Institutional Conflicts of Interest

1. The ICOI Committee shall evaluate potential ICOIs and provide the committee’s written conclusions and recommendations, if any, for ICOI management to the institutional official with the relevant decision-making authority and that official’s direct or indirect supervisor (as necessary and appropriate for the proper management of the ICOI), with a copy to the President and the Compliance Office. A copy of any conflict management plan for the President also will be provided to the Chancellor and Executive Vice Chancellor for Health Affairs of the UT System. Final authority for the management of ICOIs rests with the President.
2. A management plan may impose any condition and prescribe any action necessary to manage an ICOI to ensure that the institutional activity is free from bias or the appearance of bias. A management plan must be in the form of a written agreement and must:
 - a. Provide that the institutional official(s) acknowledge receipt of the plan and understand the requirements of this policy and required actions and other terms of the plan, including the time frames for required actions; and
 - b. Clearly identify each specific person responsible for monitoring compliance with the management plan.
3. Conflict management plans should identify and ensure adequate coordination between each individual, department, center, office or working unit necessary to the plan to ensure the integrity of UT Southwestern’s academic, research, and clinical enterprises. Each institutional official, department, center, office, or other working unit under a management plan shall comply fully and promptly with the plan, and each person, department, center, office, or other working unit identified in the management plan as having responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance.
4. In generally discharging its responsibilities to assess and manage potential ICOIs, the ICOI Committee shall take as its point of departure the overarching imperatives of preserving both the reality and appearance of integrity, honesty, accountability, and transparency in institutional decision-making regarding research, education, clinical care, business transactions, investments, or other activities. In determining whether and how to manage a potential ICOI, the fact that a situation could subject UT Southwestern to criticism, embarrassment, or litigation should be considered.
5. In assessing and managing potential ICOIs related to research that does not involve human subjects, the ICOI Committee should conduct its case-by-case analysis with due regard for the following factors, among others:
 - a. The nature of the science;

- b. The nature of the financial interest;
 - c. The nature of the overlapping interests;
 - d. How closely the financial interest is related to the research;
 - e. The degree to which the financial interest may be affected by the research;
 - f. The degree of risk that any overlapping and conflicting interests pose to the integrity (and reasonable appearance of integrity) of the research; and
 - g. The degree to which the ICOI can be effectively managed.
6. In assessing and managing potential ICOIs related to human subjects research, the ICOI Committee shall begin from the default position that either UT Southwestern’s significant outside financial interest or the relevant institutional official(s)’ substantial interest in a business entity should be eliminated, or that the research should not be conducted at or under the auspices of the University. The ICOI Committee may approve conducting the research at or under the auspices of the University; however, if it determines that compelling circumstances warrant proceeding with the research at the University, and that an effective ICOI management plan can be implemented under the circumstances to fully protect the welfare of human research participants and the integrity of the University’s research. Whether the circumstances are “compelling” and sufficiently warrant proceeding with the research under an effective ICOI management plan will depend in each case upon an analysis of all the factors identified in the preceding paragraph, among others, as well as an assessment of:
- a. the degree of risk that any overlapping or conflicting interests pose to the welfare of human research participants; and
 - b. whether the University is uniquely qualified, by virtue of distinctive resources (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and appropriately safeguard the welfare of the human research participants involved.
7. If the ICOI Committee determines that there are compelling circumstances for allowing the research to proceed in the presence of the ICOI *without* elimination or significant reduction of the financial interest, those circumstances should be documented in the ICOI Committee report on the matter. Management plans for ICOI arrangements should be designed to effectively address the: (i) nature of the conflict; (ii) specific risks to human research participants, if applicable; (iii) actual or perceived risk to the integrity of the research as a result of the conflict; and (iv) actual or perceived risk to the reputation of the University.
8. The ICOI Committee is authorized to develop guidelines and procedures for specific categories of ICOIs that present minimal risk to the integrity of the research and no risk for human research participants and that can be handled administratively with pre-defined management plans and documentation. Such cases will be reviewed by the ICOI Committee.
9. In crafting case-specific ICOI management plans, the ICOI Committee may in its discretion include one or more of the following management strategies among any others it may devise:
- a. Divesting the institution of an equity interest in an outside entity performing research on campus;
 - b. Placing the conflict-causing economic interests (e.g., investment interests) in an independent management relationship that contractually removes control of the interests from the covered individual (examples may include a blind or double-blind trust, a non-self-directed mutual fund or IRA, or a financial or legal advisor holding the interests in escrow).

- c. For research activities, the following may be included:
 - i. Declining to perform research in which the institution has a financial stake (beyond the funding of the research itself);
 - ii. Disclosure of the ICOI in public presentations and publications, and to all individuals, including (but not limited to) graduate students and other trainees, engaged in the design, conduct, or reporting of the research;
 - iii. Increasing segregation between decision-making regarding financial interests and any research or other campus activities;
 - d. For research activities involving humans, the following may be included:
 - i. Use of an external IRB;
 - ii. External monitoring of the study, particularly endpoint assessments;
 - iii. Use of an external Data Safety Monitoring Board (“DSMB”) or similar review board to evaluate the design, analytical protocols, and primary and secondary end-point assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
 - iv. Disclosure of the ICOI in informed consent processes;
 - v. Disclosure of the ICOI to other centers in a multi-center trial;
 - vi. Disclosure of the ICOI to sponsors of research as required by the sponsor or any applicable regulations and laws;
 - e. Recusal of an institutional official from decision-making or participation in an activity that would directly or indirectly involve the official’s financial interests (including recusal from the chain of authority over a project and possibly over salary, promotion, and space allocation decisions affecting subordinates);
 - f. Transfer of professorial responsibilities (and/or decision-making authority within a proscribed area) to someone who is conflict free; or
 - g. Requiring oversight of decision-making or participation in an activity by an independent third party.
10. Where individual conflicts of interest need to be managed in parallel with institutional conflicts of interest, the ICOI Office will be responsible for coordinating management activities.
11. In certain cases, the ICOI Committee may find that an individual or institutional activity presents a conflict of interest that is incompatible with the institutional official’s responsibilities, such that management is impossible or impractical. The following cases are illustrative of unmanageable conflicts of interest:
- a. When the institutional official has a responsibility to another outside entity so that the individual is unable to fulfill his or her institutional responsibilities;
 - b. When the institutional official has commitments that are counterproductive to or undermine each other;
 - c. When the institutional official seeks to use or provide, or actually uses or provides, a third party unauthorized access to unpublished other confidential or proprietary information of UT Southwestern; or
 - d. When the institutional official exercises his or her authority for a purchase or contract and for which the institutional official or covered family member receives a direct financial benefit.

Implementation and Monitoring of Management Plans

1. The institution will provide for regular review of Statements to determine individual and institutional compliance with this policy.
2. Additional monitoring of, and assistance with, compliance with ICOI management plans will be performed by the COI Office.
3. Instances of deliberate breach of this policy, including failure to submit a Statement as required by [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#); failure to provide additional information requested by UT Southwestern; knowingly violating applicable state law, the *Rules and Regulations* of the Board of Regents of the UT System, or this policy; or failure to comply with a management plan may subject the covered individual to disciplinary action under UT Southwestern and UT System policies.

Maintenance of Records

1. Records regarding the identification, review and management of institutional conflicts of interest, including related Statements, the ICOI Committee's conclusions and recommendations, and other records of institutional actions, shall be retained for the longer of at least three years after:
 - a. The date of creation;
 - b. The date of termination or completion of a research award or contract, or the submission of the final expenditure report, for research identified in a disclosure Statement; or
 - c. The date of final resolution of any investigation, audit, or similar action involving the records.
2. UT Southwestern will provide for a central repository for records related to institutional conflicts of interest.
3. The President or designee shall provide the Chancellor of the UT System or designee with copies of all guidelines, procedures, and forms used by UT Southwestern relating to institutional conflicts of interest and shall ensure that the Chancellor receives copies of any revised guidelines, procedures, and forms related to the implementation of the revision.
4. This policy and any updates will be accessible through the institution's public website, and printed copies will be made available upon written request. The ICOI Committee shall treat all materials received as a part of its review process and all ICOI Committee proceedings as confidential, and records and proceedings may be used by the ICOI Committee or its members only in the exercise of proper committee functions. Where human subjects research is involved, information may be shared with the appropriate IRB as necessary.
5. All records discussed in this policy are subject to the Texas Public Information Act. Any written request for records discussed in this policy must be forwarded immediately upon receipt to the Office of the Vice President for Legal Affairs.

RESPONSIBILITIES

The **President** shall:

- Oversee implementation of this policy;
- Appoint (or have a designee appoint) an ICOI Committee and its chair as prescribed by this policy; and
- Have final responsibility for management of ICOIs as prescribed by the ICOI Committee.

The **ICOI Committee** shall:

- Meet as necessary to identify and review ICOI issues;
- Develop management plans for potential ICOIs;

- Monitor compliance with management plans;
- Perform any other such tasks as assigned by the President.

The **COI Office** shall assist the ICOI Committee in administering and enforcing this policy.

Institutional officials shall:

- Treat their institutional responsibilities to UT Southwestern as their primary professional obligations;
- Act in a manner consistent with their assigned institutional responsibilities;
- Exercise reasonable care to avoid situations that may create a conflict of interest or conflict of commitment with their institutional responsibilities;
- Disclose activities as required by [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#) and recuse themselves from material involvement in any business transaction involving purchasing, procurement, or contracting for products or services (including, without limitation, products or services used in the delivery of patient care, course materials or other educational tools, or maintenance or construction of University equipment or facilities) from an entity if the official or a covered family member has a substantial interest in the business entity involved in the transaction.
- Comply fully and promptly with any management plan prescribed by the ICOI Committee.

DEFINITIONS

Business Entity – any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust.

Conflict of Commitment – occurs when the time or effort an employee devotes to an outside activity directly and or significantly interferes with the fulfillment of assigned institutional responsibilities, or when the employee uses UT Southwestern property without authority in connection with the employee’s outside employment, board service, or other activity. Exceeding the amount of total time permitted for approved outside activities creates the appearance of a conflict of commitment.

Conflict of Interest – a significant outside interest of a UT Southwestern employee or one of the employee’s covered family members that could directly or significantly affect the proper discharge of the employee’s institutional responsibilities. The proper discharge of an employee’s institutional responsibilities could be directly and significantly affected if the employment, service, activity, or interest: (1) might tend to influence the way the employee performs his or her institutional responsibilities, or the employee knows or should know the interest is or has been offered with the intent to influence the employee’s conduct or decisions; (2) could reasonably be expected to impair the employee’s judgment in performing his or her institutional responsibilities; or (3) might require or induce the employee to disclose confidential or proprietary information acquired through the performance of institutional responsibilities.

Compelling Circumstances - Facts sufficient to rebut the presumption that either the financial interest should be eliminated or the research should not be conducted at the institution. These facts may include a review of the nature of the research, the magnitude of the financial interest, the degree of risk to the research subjects, the extent to which the financial interest is amenable to effective oversight and management, the unique qualifications of the institution, and any other factor deemed relevant by the ICOI committee.

Covered Family Member (of an Institutional Official) – includes any of the following:

- A spouse;
- A dependent child or stepchild;
- Any other person financially dependent on the institutional official; and

- Any other person with whom the institutional official has joint financial interests, such that an objective third party could reasonably conclude that the institutional official's decisions or other exercise of institutional responsibilities could be influenced by their effect on the other person's financial interest.

Any person may meet the above definition and be identified as a covered family member without regard to whether a legal or biological family relationship exists with the institutional official.

Financial Interest – anything of monetary value, including without limitation salary or other payments for services (e.g., compensation for consulting; speaking; advising; serving on a Board of Directors or as an officer, trustee, or other executive or management position; editorial compensation; etc.); investment interests (e.g., common or preferred stock, options or other derivatives, partnership interests or shares, etc.); intellectual property rights (e.g., patents, copyrights, royalties from such rights, etc.); reimbursements including travel expenses; gifts; or other income (e.g., any other compensation or benefit from a single business entity not otherwise described above).

Gift (to an Institutional Official) – means anything of value and includes meals, services, and entertainment that are not provided as a part of appropriately sanctioned educational activities (e.g., scientific, educational, or professional meetings).

Gift (to UT Southwestern) – means a commitment in the form of cash, pledge, securities, bequest/trust distributions, life insurance, real estate, in-kind, and other transferable assets received by UT Southwestern from an individual, corporation, foundation, or other entity that is given with the intent of supporting UT Southwestern's mission and programs, with no expectation of benefit other than UT Southwestern expending the contribution for any mutually agreed upon purposes. The contribution is a nonreciprocal transfer in that there is no implicit or explicit statement of exchange, purchase of services, or provision of exclusive information. If the contributor receives benefits in return for the contribution, the amount of the gift recorded and reported is reduced by the fair market value of all benefits given, according to U.S. Internal Revenue Service (IRS) regulations. A restricted gift must be used by UT Southwestern only for the specified purpose designated by the donor. An unrestricted gift may be used by UT Southwestern in accordance with UT Southwestern and UT System policies. Under no circumstances may UT Southwestern accept gifts to benefit an individual unless the donor is exempt from federal income taxes as defined by the Commissioner of Internal Revenue.

Human Subjects Research – all research meeting the definition of "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulations.

Institutional Conflict of Interest (ICOI) – may exist when the financial interests of UT Southwestern or of an institutional official, acting within his or her official capacity on behalf of the institution, may compromise or bias, or appear to compromise or bias, the purchasing activities, investments, research, teaching, clinical care, outreach, or other activities of the institution.

Institutional Official – for purposes of this policy, includes the President; all levels of provosts, vice presidents, and deans; department chairs, center directors, and division chiefs; department heads; chairs of institutional standing committees; all members of specific institutional standing committees as determined by the ICOI committee; any employee with delegated signature or purchasing authority of \$15,000 or more for a single purchase on behalf of UT Southwestern; and any other employee designated as an institutional official by the President.

Institutional Responsibilities – any duties or responsibilities assigned to a position, including without limitation essential and other functions, research, research consultation, teaching, administrative responsibilities, professional practice, institutional committee membership, or service on an institutional panel.

Investment Interest – means common or preferred stock (in any form or class), warrants, options or other derivatives, partnership interests or shares, etc., where the selection or disposition of the interest is directly controlled by the individual.

Management Plan – a plan imposing any condition or prescribing any action necessary to manage a conflict of interest or conflict of commitment, including an action reducing or eliminating the conflict of interest or conflict of commitment.

Outside Entity – any business entity, association, organization, or any other legal entity organized for profit or non-profit (charitable) purposes, except for (a) UT Southwestern-affiliated hospitals or (b) any non-profit health-care corporation or any other entity controlled by, controlling, or under common control with UT Southwestern.

Research – means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Significant Financial Interests of UT Southwestern – for purposes of this policy, means:

- Cumulative gifts within the past 10 years of \$1,000,000 or more from any person or outside entity; cumulative gifts to an institutional department of \$100,000 or more from any person or outside entity; or cumulative gifts to conduct "research" to an individual's institutional account of \$5,000 or more from any person or outside entity;
- Payments from a person or outside entity for the licensing of intellectual property that, on aggregate, exceed \$250,000 per calendar year;
- Investment interests in entities held by UT Southwestern, including investment interests resulting from institutional technology transfer activities, where (i) such investment interests have a value of more than \$1,000,000 in the case of a publicly-traded entity, or (ii) in the case of a non-publicly traded entity, any investment interest in an outside entity where the valuation of the entity exceeds \$1,000,000.

Statement of Financial Interest and Outside Activities ("Statement") – the disclosure form that identifies all outside activities of the covered individual and covered family members (as defined in [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#)).

Substantial Interest in a Business Entity (for an Institutional Official) – for purpose of this policy, means (1) for any single, publicly traded business entity, any investment interests as valued on the date of disclosure by reference to public prices or other reasonable measures of fair market value exceeds \$5,000; (2) for any single, non-publicly traded business entity, any investment interest; or (3) service as an officer. The term does not include investment interests in mutual funds or retirement accounts, so long as the individual does not directly control the investment decisions made in those vehicles.

RELATED STATUTES, POLICIES, OR STANDARDS

Chapter 572, Texas Government Code

Chapter 36, Texas Penal Code

UT System Board of Regents' *Rules and Regulations* 30104 Conflict of Interest, Conflict of Commitment, and Outside Activities

UTS123 Policy on Service on Outside Boards

UTS180 Conflicts of Interest, Conflicts of Commitment, and Outside Activities

UTS175 Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research

UTS189 Institutional Conflicts of Interest

[ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#)

[EMP-158 Outside Activities \(Including Outside Employment or Board Service\)](#)

[EMP-159 Employment in Multiple State Positions](#)

[FIM-601 Gifts - Solicitation, Acceptance, Processing, and Acknowledgement](#)

[RES-401 Financial Conflicts of Interest in Research: Disclosure, Management, and Reporting](#)

CONTACTS/FOR FURTHER INFORMATION

Conflict of Interest Office 214-648-5300

POLICY HISTORY

August 22, 2019: Updated definition of “Institutional Official,” allowing the ICOI committee to determine which institutional standing committees should be considered “Institutional Officials.”

May 9, 2018: Revised to align with UTS 189 Institutional Conflicts of Interest.

November 20, 2014: Developed as new policy; published as ETH-304 Institutional Conflicts of Interest.