

# UT SOUTHWESTERN POLICY HANDBOOK

## RES-401 FINANCIAL CONFLICTS OF INTEREST IN RESEARCH: DISCLOSURE, MANAGEMENT, AND REPORTING

### CHAPTER 12: RESEARCH AND SPONSORED PROGRAMS

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#### ADMINISTRATIVE INFORMATION

Responsible Office: Conflict of Interest Office  
Executive Sponsor: Executive Vice President for Academic  
Affairs & Provost and Vice Provost and Dean for Research  
Effective Date: 12/23/2013  
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Because of the length of this policy, the following links are provided as a guide to its sections.

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## POLICY RATIONALE

As a state agency and university, UT Southwestern has a responsibility to the public to promote an environment that endorses the highest standards of integrity, honesty, and objectivity in its research activities. At the same time, independent relationships with outside entities established by faculty, staff, and students can enhance the institution's research and educational missions, while also presenting opportunities for personal financial gain. Additionally, UT Southwestern has an obligation to commercialize technologies derived from faculty research for the public good, and these activities frequently result in royalty income for the faculty inventors.

Faculty and staff engagement in relationships with outside entities is not in principle unacceptable, and commercialization activities can align with the university's missions, but in practice, such interactions must be carefully managed. If the potential or actual conflicts of interest created by these relationships and activities are not appropriately disclosed, reduced, managed, or eliminated, they will undermine the public's trust in the research and business conducted at UT Southwestern, and they may violate federal or state law and regulations, as well as policies of The University of Texas System (UT System).

To meet the challenges presented by these competing values, missions, and obligations, UT Southwestern has developed this policy on financial conflicts of interest in research.

## POLICY TEXT

The primary responsibility of a covered individual (as defined in this policy) must be at all times to his or her institutional responsibilities at UT Southwestern. No covered individual may engage in any outside relationship with a business entity if that relationship improperly influences decisions related to the covered individual's institutional responsibilities, either leading to personal financial gain or advantage or otherwise causing or appearing to cause bias in the design, conduct, or reporting of research. Covered individuals must disclose and structure their relationships with outside entities to enable the review and management of any possible conflicts of interest with their institutional responsibilities. Covered family members will also be included in the analysis of a perceived or actual conflict of interest. Covered individuals whose appointments are less than full-time are expected to devote full professional loyalty, time, and energy to their institutional responsibilities according to their agreed-upon time commitments.

Every covered individual is required to acknowledge this policy, to comply with all of its requirements, and to adhere fully to any management plans developed under this policy. This policy applies in addition to, and not instead of, general UT Southwestern or UT System policies, such as policies on standards of conduct, as well as other policies or statutes governing disclosure of activities and financial interests.

If a specific law or regulation provides different requirements than this policy, the more stringent requirement applies.

## SCOPE

This policy applies to all employees, students, trainees, and individuals engaged in research under UT Southwestern's oversight who are covered individuals as defined in this policy.

## PROCEDURES

### I. Required Disclosure of Financial Interests ("Statement") by Covered Individuals [\[back to top\]](#)

1. Every covered individual as defined in this policy must complete a Statement of Financial Interests in accordance with [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#) and disclose outside activities in accordance with [EMP-158 Outside Activities \(Including Outside Employment or Board Service\)](#).

2. The Conflict of Interest (COI) Official, COI Office, COI Committee, or President of UT Southwestern may request further information about any activity or financial interest in order to determine if a conflict of interest or commitment exists.

## II. Review of Statements [\[back to top\]](#)

1. The COI Office will assess completed Statements to determine if any conflicts of interest or commitment related to research exist.
2. Statements that report possible conflicts of interest related to research, including human subjects research, will be initially assessed by the COI Office using the considerations set forth in this policy for determination of whether any financial interest disclosed is related to the research in which the covered individual is engaged, and if so, whether a conflict of interest exists.
  - (a) Routine interests, including interests of \$4,999 or less or renewal of an existing management plan, may result in the COI Office developing and submitting a management plan directly to the COI Official for approval.
  - (b) For non-routine interests, or at the discretion of the COI Official, the review of a Statement will be referred to the COI Committee for assessment. The COI Committee will determine if the conflict is not permissible, or, if permissible, will develop for the COI Official's approval a management plan in cooperation with the covered individual and other individuals as applicable.
3. The COI Office will document the review of Statements. If required by a granting agency, notice of review will be forwarded in accordance with the agency's policy.
  - (a) When Statements are updated, a re-review will occur, even when no prior conflicts of interest were identified.
  - (b) For Statements reporting conflicts of interest, records will be maintained, identifiable to any grant awarded to the covered individual, showing that review has taken place and that a management plan has been developed and implemented.
4. Neither UT Southwestern nor a covered individual may expend research funds unless it has been determined that no conflicts of interest exist or, if any conflicts do exist, these conflicts are manageable in accordance with the terms of a management plan. UT Southwestern maintains a strong presumption against permitting any covered individual with significant financial interests from participating in related research. To overcome this presumption, a covered individual must assert and demonstrate to the COI Committee that compelling circumstances exist for the covered individual's participation in the related research in question.
  - (a) In considering whether compelling circumstances exist, the COI Committee will evaluate the following:
    - i. the nature of the research;
    - ii. the magnitude of the financial interest and its relation to the research;
      1. the extent to which the research could directly and substantially influence the financial interest;
    - iii. the degree of risk to the research subjects inherent in the protocol;
    - iv. the extent to which the financial interest is amenable to effective oversight and management; whether the covered individual is uniquely qualified by virtue of expertise and experience such that the research could not be otherwise conducted safely or effectively without the covered individual; and any other factor deemed relevant.

- v. Any other supporting information as requested by the COI Committee.

### III. Considerations in Reviewing Statements Involving Human Subjects Research [\[back to top\]](#)

1. Statements that report conflicts of interest in human subjects research will be assessed in light of the special ethical responsibility UT Southwestern and covered individuals have to protect the safety and well-being of human research subjects. Financial interests held by covered individuals conducting human subjects research may compromise or appear to compromise this ethical responsibility. Examples of such interests include the following:
  - (a) Serving as a research study team member on a clinical study supported by or evaluating the products or devices of an outside entity, and receiving (or a covered family member receiving) salary, consulting, advisory, or speaking fees, honoraria, gifts, or other payments from the same outside entity;
  - (b) Serving as a study team member on a clinical study supported by or evaluating the products or devices of an outside entity, and holding (or a covered family member holding) an investment interest in the same outside entity; or
  - (c) Serving as a study team member on a clinical study supported by or evaluating the products or devices of an outside entity, and holding (or a covered family member holding) a position as a member of the board of directors, an officer, or other executive or management position of the same outside entity.
2. When the COI Committee or COI Official has instituted a management plan and the plan has been agreed to by the covered individual, the covered individual may be permitted to conduct Institutional Review Board (IRB)-approved human subjects research. The COI Office provides all management plans to the Human Research Subjects Protection Program (HRPP) Office. The IRB, at its discretion, may impose more strict requirements regarding the management of conflicts of interest during its review process. Alternatively, if the IRB disagrees with the management plan, it can seek to have the COI Committee re-assess the plan prior to approval of the IRB protocol.

### IV. Considerations in Reviewing Statements Related to Commercialization Activities [\[back to top\]](#)

1. Through the Office of Technology Development, UT Southwestern works to create relationships with outside entities – via licensing, sponsored research agreements, supporting new start-up companies, or other means – to commercialize intellectual property developed from the research activities of UT Southwestern faculty, employees, trainees, and students, for the public good. Inventor participation in these commercialization activities can be critical to the success of these activities. It is just as important that these activities do not compromise or appear to compromise the integrity of the underlying research. Statements that report conflicts of interest in research with related commercialization activities will be assessed in light of these considerations.
2. Examples of such inventor participation include the following:
  - (a) Participating in sponsored research supported by an outside entity that also has licensed technology related to the sponsored research from UT Southwestern, for which the covered individual is entitled to or has received royalty income under UT Southwestern’s intellectual property policy;
  - (b) Participating in sponsored research involving the licensed technology that has been licensed for commercialization, for which the covered individual is entitled to or has received royalty income under UT Southwestern’s intellectual property policy; or
  - (c) Participation as a scientific advisory board member for a start-up outside entity that has licensed technology from UT Southwestern, holding a founder investment interest in the same outside entity, and participating in research on the same licensed technology.

3. Consequently, any research conducted in association with commercialization activities must be reviewed and, if necessary, subject to a management plan.
4. The Office of Technology Development is the designated office responsible for commercializing the intellectual property developed from research activities of UT Southwestern faculty for the public benefit. The office may consult with a covered individual who is an inventor concerning the development or commercialization of that invention. Final decisions concerning whether or how UT Southwestern develops and commercializes an invention will be made at the sole discretion of UT Southwestern. Decision-making authority for management of related conflicts of interest resides with the COI Official and the COI Committee.

## V. Elimination or Management of Conflicts of Interest [\[back to top\]](#)

1. The COI Committee can determine that the research cannot be conducted at UT Southwestern due to the nature of the conflict of interest. To eliminate the conflict of interest, the covered individual may be asked to sever the relationship that created the actual or potential conflict, or otherwise be informed that the research is not permissible.
  - (a) No covered individual may receive compensation from any person or outside entity if such compensation is conditioned upon a particular research result.
2. In the event that the COI Committee finds that the conflict is manageable, a management plan will be created. Management plans impose conditions and prescribe actions needed in order to manage a conflict of interest, including actions taken to reduce the conflict and ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include the following:
  - (a) Public disclosure of the conflict of interest in presentations and publications;
  - (b) Disclosure of the conflict to students, trainees, staff, and/or patients;
  - (c) For human subjects research, direct disclosure of the conflict of interest to research participants during the informed consent process or at other times during the research subject's participation in research;
  - (d) Appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
  - (e) Modification of the research plan;
  - (f) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - (g) Divestiture or reduction of the financial interest.
3. A management plan will be a written agreement and will include the covered individual's:
  - (a) Acknowledgement of the receipt of the plan;
  - (b) Understanding of the requirements of this policy; and
  - (c) Understanding of the identified conflicts of interest, the required actions, duration, and other terms of the plan, including time frames for required actions.
4. Management plans issued for non-research related conflicts of interests will follow the processes outlined in this policy, in accordance with [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#).

5. If circumstances warrant, it may be necessary to implement an interim management plan or other interim measures before development of a final management plan.
  - (a) If research is ongoing and a covered individual discloses a new significant financial interest related to the research, then as soon as possible but no later than the 60<sup>th</sup> calendar day after the filing of the revised Statement (as required by Public Health Service [PHS] regulation), the interests shall be reviewed to determine if a conflict of interest exists. If the COI Committee is unable to review the conflicts of interest within the 60 day timeframe, the COI Official will create an interim management plan to ensure the objectivity of the research. The interim management plan will be in place until the COI Committee is able to review the Statements.
  - (b) If the COI Office or the COI Official learns of a significant financial interest that was not disclosed or reviewed in a timely manner, then as soon as possible, but no later than the 60<sup>th</sup> calendar day after learning of the significant financial interest (as required by PHS regulation), the interest shall be reviewed to determine if a conflict of interest exists and, if so, an interim management plan or other interim management measures must be implemented to ensure the objectivity of the research.

## VI. Challenging COI Decisions [\[back to top\]](#)

1. Covered individuals may challenge a decision of the COI Office, Official, or Committee. The covered individual challenging a decision must do so in writing to the COI Official within five working days of being informed of the decision.
  - (a) The written challenge should clearly state:
    - i. the decision being challenged;
    - ii. the facts upon which the covered individual is relying; and
    - iii. the reason(s) why the decision should be changed, and the change sought.
  - (b) Incomplete challenges will not be reviewed.
  - (c) The COI Official may review challenges to routine management plans, or defer review of the challenge to the COI Committee. Any challenges to decisions made by the COI Committee will be reviewed by the COI Committee. The COI Committee may, but is not required to, consult with the covered individual in review of the challenge. The COI Committee may seek the guidance of other relevant UT Southwestern or UT System personnel as appropriate in reviewing the challenge.
  - (d) The COI Official should provide a written decision to the covered individual within 45 calendar days of receipt of the challenge.
2. If the covered individual disagrees with the COI Official or COI Committee's decision on the challenge, the covered individual may appeal the decision to the Executive Vice President for Academic Affairs and Provost, or their designee.
  - (a) The covered individual must appeal the decision on the challenge in writing to the COI Official within five working days of receipt of the challenge decision. The COI Official will review the appeal with the Executive Vice President for Academic Affairs and Provost or designee. The written appeal should clearly state:
    - i. the facts upon which the covered individual is relying;
    - ii. the reason(s) why the decision should be changed; and

- iii. the change sought.
  - (b) Incomplete appeals will not be reviewed.
  - (c) The Executive Vice President for Academic Affairs and Provost, or their designee, will review the appeal as well as the facts and reasoning of the COI Official or COI Committee. The Executive Vice President for Academic Affairs and Provost or designee may, but is not required to, consult with the covered individual, the COI Office, the COI Official or the COI Committee in review of the appeal. The Executive Vice President for Academic Affairs and Provost, or designee, may seek the guidance of other relevant UT Southwestern or UT System personnel as appropriate in reviewing the challenge.
  - (d) The Executive Vice President for Academic Affairs and Provost, or their designee, should provide a written decision to the covered individual within 30 calendar days of receipt of the appeal. The decision of the Executive Vice President for Academic Affairs and Provost or designee is final in all respects.
3. Failure of the covered individual to meet any deadline for challenging or appealing a decision will constitute a waiver by the covered individual of their ability to challenge or appeal. Failure of a covered individual to sign and acknowledge a management plan as described above within five working days of receipt also constitutes a waiver by the covered individual of their ability to challenge or appeal.
  4. Copies of challenges and appeals, as well as all associated documentation, will be maintained by the COI Office.

## **VII. Disclosure and Management Plan Compliance** [\[back to top\]](#)

1. If a financial interest is not identified or managed in a timely manner, or if a covered individual fails to comply with a management plan, the COI Official shall, along with a convened review panel, attempt to do the following within 60 calendar days after determining non-compliance, but in no event will take more than the 120 days as required by PHS regulations:
  - (a) complete and document a retrospective review to determine the extent of the non-compliance;
  - (b) determine whether research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research (determination of bias); and
  - (c) implement any administrative measures or sanctions necessary, as directed by UT Southwestern administration.
2. During the conduct of the retrospective review and determination of bias, the conflicted researcher may not participate in the planning, conduct, or reporting of related research. If circumstances warrant, the COI Official will request that the conflicted researcher's Department Chair ensure oversight of human subject and animal welfare during the review period.
3. Any retrospective review conducted shall cover key elements as specified by the federal regulations and may result in updating the Financial Conflict of Interest Report described in [Section VII](#), notifying the PHS, and submitting a mitigation report as required by federal regulations.
4. The COI Official must also refer a matter of noncompliance to the Executive Vice President for Academic Affairs and Provost for disciplinary action. If the Executive Vice President for Academic Affairs and Provost determines disciplinary actions is warranted, a covered individual may appeal the decision of disciplinary action to the President.

## **VIII. Certification and Reports to the Public Health Service (PHS)** [\[back to top\]](#)

1. Federal regulations require that each application for funding to the PHS include specific certifications and agreements in regard to this policy and conflicts of interest. Federal regulations also require that UT Southwestern make reports required by this policy related to PHS-funded research.



2. Before the expenditure of any funds under a PHS-funded research project, the COI Official or designee will make the Financial Conflict of Interest Report to the PHS awarding component in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94. In general, those regulations require a Financial Conflict of Interest Report regarding those interests that UT Southwestern determines are conflicts of interests, including conflicts of interest of sub-recipients.
  - (a) The reporting will include specific information sufficient to enable the awarding component to understand the nature and extent of the conflict of interest and to assess the appropriateness of the management plan related to the conflict of interest.
  - (b) The federal regulations require reporting within a specified period of conflicts of interest identified after an earlier report, and require annual updating of reports regarding previously disclosed conflicts of interest.

## **IX. Records and Confidentiality** [\[back to top\]](#)

1. Records are maintained in accordance with [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#). To the extent permitted by law and the requirements of this policy, all statements, other records, and information submitted to the COI Official or the COI Committee will be maintained confidentially. However, any statements, other records, or information will be made available upon written request to the agency funding research of the covered individual, and as otherwise required by law. Where human subjects research is contemplated and a potential or actual conflict exists, the Statement(s), other records and information may be shared with the appropriate IRB.
2. All records discussed in this policy may be 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.

## **X. Collaborators and Contractors** [\[back to top\]](#)

1. If research is conducted in cooperation with or through a subcontractor, contractor, or collaborator as part of a research agreement, including a person identified under applicable federal regulations as a “sub-recipient,” UT Southwestern must enter into a written agreement with the contracting party that provides legally enforceable terms that establish whether this policy or the financial conflicts of interest policy of the contracting party applies to the investigators of the contracting party.
2. If the policy of the contracting party applies to its investigators, the contracting party must certify that its policy is consistent with the requirements of any applicable regulations. If the contracting party cannot so certify, the agreement must state that the investigators are subject to this policy as covered individuals for disclosing financial interests that relate to the investigators’ research at UT Southwestern.
3. If the policy of the contracting party applies to its investigators, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to UT Southwestern. The time periods must be sufficient for UT Southwestern to make any reports required by applicable federal regulations.
4. If this policy applies to the investigators of the contracting party, the agreement must specify the time periods for the researchers to submit a Statement of Financial Interest. The time periods must be sufficient for UT Southwestern to comply with its review, management, and reporting obligations under federal regulations and this policy.

## **XI. Public Disclosure of Conflicts of Interest and Outside Activities** [\[back to top\]](#)

1. The current version of this policy will be posted on the UT Southwestern Internet website.



2. Information provided by covered individuals on their Statement will be made available to the public through the UT Southwestern Internet website according to [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#).
3. For PHS-funded research, information required to be posted will be made available to the public before the expenditure of the related PHS research funds can occur.

## RESPONSIBILITIES

### XII. Covered Individuals [\[back to top\]](#)

1. Each covered individual must annually acknowledge adherence with this policy.
2. Each covered individual must complete training as defined in [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#).
3. A covered individual's primary responsibility is to his or her institutional responsibilities. No covered individual shall conduct research or engage in any other institutional responsibilities under circumstances in which a reasonable person could infer that the research or institutional responsibilities could have been influenced by the desire for or expectation of direct or indirect personal financial gain.
4. Faculty members are responsible for the academic development of students, residents, and other trainees under their direction. Faculty members should not permit students, residents, or other trainees to participate in any research supported by an outside entity if any of the terms or conditions of participation would prevent the student, resident, or trainee from meeting any applicable degree or residency/fellowship training requirements.
5. No member of any institutional committee reviewing research at UT Southwestern may participate in any review of any project in which that member may have a significant financial interest, except to provide information requested by the reviewing committee.
6. Covered individuals must fully and promptly comply with the provisions of this policy. Timely, complete, and accurate disclosure of outside activities consistent with [ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#) is a condition of employment at UT Southwestern.
  - a. Instances of deliberate breach of this policy, including failure to submit a Statement as required in this policy; failure to provide additional information requested by UT Southwestern; knowingly filing an incomplete, erroneous, or misleading Statement; knowingly violating applicable state law, the *Rules and Regulations* of the Board of Regents of the UT System, or this policy; failure to comply with a management plan; or failure to complete required training may subject the covered individual to disciplinary action under UT Southwestern and UT System policies, as well as possible enforcement actions mandated by a granting agency.
  - b. Disciplinary action may include termination of employment, non-renewal of any faculty appointment, debarment from eligibility for federal funds, or possible prosecution under state or federal law.
7. For a covered individual who is not an employee of UT Southwestern, compliance with this policy is a condition of participating in research at UT Southwestern. UT Southwestern may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

### XIII. COI Official, the COI Committee, and the COI Office [\[back to top\]](#)

1. The President, or his or her designee, shall appoint the Conflict of Interest Official (or COI Official) for UT Southwestern. The COI Official is responsible for development, implementation, and enforcement of this policy; serving as the Chair of the COI Committee; ensuring covered individuals participate in required training; and other duties as assigned by

the President. Service as the COI Official is in addition to any other capacities in which the person serves UT Southwestern.

2. The President, or designee, shall appoint a COI Committee to assist the COI Official in developing policy, reviewing conflict of interest or conflict of commitment issues, developing management plans for potential conflicts of interest, monitoring compliance with management plans, and any other such tasks as assigned by the President or the COI Official.
  - a. The COI Committee will be comprised of individuals with sufficient independence, expertise, and seniority. Voting members will include faculty and staff involved in a cross-section of research topics.
  - b. Invited guests will be non-voting and participate in COI Committee meetings and other activities as needed. Guests will represent the COI Office, Office of Technology Development, Legal Affairs, Contracts Management, and other groups as designated by the COI Official.
  - c. At least four meetings a year will be held.
  - d. Quorum will be made with the majority of voting members present.
3. The COI Official may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.
4. The COI Office shall assist the COI Official and COI Committee in administering and enforcing this policy.

#### XIV. UT Southwestern [\[back to top\]](#)

1. Federal regulations require UT Southwestern to notify the PHS of instances in which a covered individual's failure to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require UT Southwestern to take action appropriate to maintaining objectivity in research. UT Southwestern will make information available to the Department of Health and Human Services (HHS) or the PHS awarding component as required by federal regulations.
2. If HHS determines human subjects research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a significant financial interest that was not managed or reported by UT Southwestern by federal regulations, UT Southwestern will require the covered individual involved to disclose the conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
3. UT Southwestern will provide for regular audits of Statements to determine individual and UT Southwestern compliance with this policy.

## 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.

**Compelling Circumstances** – are 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 COI Committee.

**Conflict of Interest (COI)** – refers to any situation in which any financial interest of a covered individual or covered family member could cause or appear to cause bias in the design, conduct, or reporting of research, or otherwise directly or significantly affect the proper discharge of the covered individual’s institutional responsibilities. The proper discharge of institutional responsibilities (including the design, conduct, or reporting of research) could be directly or significantly affected if a covered individual’s or covered family member’s employment, service, activity, or interest:

- 1) might tend to influence the way the covered individual performs his or her institutional responsibilities, or the covered individual knows or should know the interest is or has been offered with the intent to influence the covered individual’s conduct or decisions;
- 2) could reasonably be expected to impair the covered individual’s judgment in performing his or her institutional responsibilities; or
- 3) might require or induce the covered individual to disclose confidential or proprietary information acquired through the performance of institutional responsibilities.

**COI Committee** – the Conflict of Interest (COI) Committee is an Institutional Standing Committee. Members are appointed by the President. The Committee assists the COI Office in developing policy, reviewing conflict of interest or commitment issues, developing management plans, and monitoring compliance.

**COI Official** – the Conflict of Interest (COI) Official is appointed by the President, or their designee, and is responsible for the development, implementation, and enforcement of this policy.

**Covered Family Member (of a Covered Individual)** – includes any of the following:

1. A spouse;
2. A dependent child or stepchild;
3. Any other person financially dependent on the covered individual; and
4. Any other person with whom the covered individual has joint financial interests, such that an objective third party could reasonably conclude that the covered individual’s decisions or other exercise of institutional responsibilities could be influenced by their effect on the other person’s financial interest.
5. 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 covered individual.

**Covered Individual** – The following individuals are considered to be covered individuals for this policy:

1. Employees who have been determined to be exempt from the Fair Labor Standards Act (FLSA) and are, therefore, not entitled to overtime pay. It also includes employees who are not exempt from the FLSA if they are authorized to execute contracts on behalf of the University or who because of their job duties at the University have authority to exercise discretion with regard to the award of contracts or other financial transactions. This definition includes staff assigned to professional and administrative positions and staff assigned to classified positions.
2. Any research study team members regardless of their employment status with UT Southwestern, including graduate students and post-graduate trainees, but not including high school or undergraduate students.
3. Medical school students.
4. Members of institutional committees, as determined annually by the COI Committee, including non-affiliated members.

5. Any employee authorized to execute contracts on behalf of UT Southwestern or who, because of their job duties, has authority to exercise discretion with regard to the award of contracts or other financial transactions (including research or technology license agreements); executive officers; and employees involved in procurement activities.
6. Faculty members including individuals with full or part time academic appointments with UT Southwestern, including those individuals holding academic appointments with an adjunct title (with or without pay). Voluntary or emeritus faculty are not considered covered individuals unless they serve as research study team members.
7. Any individual designated as a covered individual by the President of UT Southwestern or COI Official who would otherwise not be a covered individual.

**Employees Involved in Procurement Activities** – An employee who is authorized to make single purchases valued at or above of \$15,000 and who make decisions regarding such purchases, including:

1. contract terms or conditions on a contract;
2. who is to be awarded a contract;
3. preparation of a solicitation for a contract; or
4. evaluation of a bid or proposal.

**Executive Officer** – includes, but is not limited to, the President; all individuals who report directly to the President (other than administrative support positions); and any employee who exercises broad and significant discretion over key institution functions.

**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).

**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.

**HRPP** – Human Research Protections Program which includes the IRB and other support functions.

**Institutional Responsibilities** – any duties or responsibilities of a covered individual on behalf of UT Southwestern, including without limitation essential and other functions, research, research consultation, teaching, administrative responsibilities, professional practice, institutional committee membership, or service on an Institutional Standing Committee or other convened group.

**IRB** – Institutional Review Board which is an Institutional Standing Committee. Members are appointed by the President. The IRB is a federally-mandated internal committee that must review and approve all human subjects research prior to initiation.

**Investment Interest** – 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. 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.

**Outside Activity** – any activity, including outside employment, board service, speaking engagement, or non-remunerated activity that is otherwise not pre-approved or does not require disclosure.

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

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

**Research Study Team Members** – all principal investigators, sub-investigators, or other persons involved in a research project, regardless of title or position, who are responsible for the design, conduct, and/or reporting of research.

**Significant Financial Interest** – a financial interest consisting of one or more of the following interests of a covered individual or covered family member:

1. From any single, publicly traded business entity – any salary, consulting fees, honoraria, paid authorship or other payments for services received in the preceding 12 months, and any investment interests as valued on the date of disclosure by reference to public prices or other reasonable measures of fair market value, all of which, when aggregated for the covered individual and covered family members, exceeds \$5,000;
2. From any single, non-publicly traded business entity – any salary, consulting fees, honoraria, paid authorship, or other payments for services received in the preceding 12 months, all of which, when aggregated, exceeds \$5,000, and/or any investment interest in the business entity;
3. Intellectual property and royalties distributed by an outside entity – upon receipt of income related to any royalties (including annual royalties or royalties on sales of licensed products), license fees (including up-front license fees, milestone payments, and performance payments), or other compensation (including investment interests or proceeds from sales of investment interests), or upon receipt of income related to agreements to share in royalties (including annual royalties or royalties on sales of licensed products), license fees (including up-front license fees, milestone payments, and performance payments), or other compensation (including investment interests or proceeds from sales of investment interests) with respect to intellectual property;
4. Intellectual property and royalties distributed by UT Southwestern or UT System when engaged in clinical research – upon receipt of income related to any royalties (excluding royalties on sales of licensed products), license fees (including up-front license fees, milestone payments, and performance payments), or other compensation (including investment interests or proceeds from sales of investment interests), or upon receipt of income related to agreements to share in royalties (excluding royalties on sales of licensed products), license fees (including up-front license fees, milestone payments, and performance payments), or other compensation (including investment interests or proceeds from sales of investment interests) with respect to intellectual property;
5. Gifts – a single gift to a covered individual or his or her immediate family members from a business entity received in the preceding 12 months that exceeds \$250 in value, or multiple gifts from a single business entity that in the aggregate exceed \$250 in value, other than gifts from a covered family member; or
6. A fiduciary position held by the covered individual or a covered family member in a business entity in the preceding 12 months, including a position as a member of the board of directors, an officer, or other executive or management position, for which the covered individual received any form of remuneration or reimbursement for expenses.
7. Significant financial interests do not include salary, or other remuneration paid by UT Southwestern (if the covered individual is currently employed or otherwise appointed by UT Southwestern); income from seminars, lectures, teaching engagements, or service on an advisory committee or review panel sponsored by a federal, state, or local

government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; income from investment vehicles such as mutual funds or retirement accounts in which the covered individual does not directly control investment decisions made in those vehicles; or travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

**Statement of Financial Interest (“Statement”)** – the electronic disclosure form that identifies all financial interests and outside activities of the covered individual and covered family members. For purposes of compliance with this policy, it also identifies whether the covered individual is engaged in research sponsored by, or is evaluating the products or devices made by, the business entities in which financial interests were reported.

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## RELATED STATUTES, POLICIES, OR STANDARDS

Rule 30104 & Series 90000, *Rules and Regulations* of the Board of Regents of the University of Texas System

UT System Policy UTS 175 Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research

UT System Policy UTS 180 Conflicts of Interest, Conflicts of Commitment, and Outside Activities

42 CFR Part 50 & 45 CFR Part 94

Section 51.912, Texas Education Code

Chapter 572, Texas Government Code

[INP-101 Technology Development and Intellectual Property Management](#)

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

[ETH-304 Institutional Conflicts of Interest](#)

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

## FORMS, TOOLS, ONLINE PROCESSES

<http://www.utsouthwestern.net/coi-oe>

## CONTACTS/FOR FURTHER INFORMATION

Conflict of Interest Office 214-648-5300

## POLICY HISTORY

July 6, 2018: To be consistent with other existing policies, updated the definitions of the terms “Institutional Responsibilities,” “Investment Interest,” and “Outside Entity.”

June 29, 2018: Completed full review; updated policy as necessary.

September 19, 2016: Updated policy to clarify its references to Statements and definitions of covered individual and employees involved in procurement activities.

December 23, 2013: Developed as new policy; published as RES-401 Financial Conflicts of Interest in Research: Disclosure, Management, and Reporting.