UT Southwestern Medical Center

Human Research Protection Program Departmental Policy and Procedure

5.3 Financial Conflict of Interest Management

Effective Date: June 5, 2026

I. Policy Statement

a. 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 university research for the public good, and these activities frequently result in royalty income for the university inventors.

b. 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 perceived, 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 policies to address financial conflicts of interest in research.

c. To meet the above stated goals, UT Southwestern has centralized the Conflict of Interest (COI) management program within the Conflict of Interest Office (COIO). A standing committee is charged to review the disclosure forms submitted to make recommendations on how to manage, mitigate or eliminate

individual conflicts of interest and commitment as they arise. The COI Committee exists to protect the integrity of all faculty and investigators at UT Southwestern, and maintain the public trust. The COI Committee carries out this charge in a manner that is intended to foster, not hinder, research and other entrepreneurial faculty relationships.

d. UT Southwestern Institutional Review Boards (IRBs) evaluate individual financial Conflict of Interest management plans issued by the COI Committee (see Policy Res-401 Financial Conflicts Of Interest In Research: Disclosure, Management, And Reporting). Principal Investigators and study team members involved in the conduct or support of human subject research in which UT Southwestern is engaged must disclose related financial conflict of interest as a part of the initial study application, at each continuing review, and update as needed with modifications.

e. UT Southwestern HRPP also considers Institutional Conflict of Interest (see Policy Eth-304 Institutional Conflicts Of Interest). Where institutional conflicts may arise from royalties or intellectual property rights associated with a technology that is the subject of the research or from UT Southwestern financial interests or of its Institutional Officials, UT Southwestern manages these potential institutional conflicts of interest in addition to the management of any related individual conflict of interest on a protocol specific basis.

f. The final determination regarding the COI management is made by the IRB (UTSW IRB or external IRB) when the study involves human subjects.

g. Humanitarian Use Device (HUD) protocols do not constitute research and are not covered by this policy. Therefore Financial Interests or COI Management Plans are not required to be considered with initial protocol application or at the time of continuing review. UT Southwestern will address these as part of addressing potential clinical conflicts of interest

II. Scope

This policy applies to all "covered individuals" engaged in the design, conduct, and/or reporting of human subjects research under UT Southwestern's HRPP (Res-151: Human Research Protection Program). "Covered Individuals" must comply with the UT Southwestern's Policy Res- 401 Financial Conflicts Of Interest In Research: Disclosure, Management, And Reporting; disclosure process and management plans, as applicable; sponsor requirements and federal regulations concerning conflict of interest management.

a. Covered Individuals for the purposes of this policy include:
    i. Faculty members;
    ii. Study team members (including students and post-graduate trainees); and
    iii. Non-UT Southwestern employees and trainees that participate in human subject research protocols under the authority of UT Southwestern IRBs.
b. Covered individuals' disclosures must include family members which are defined as:
    i. a spouse;
    ii. a dependent child or stepchild;
    iii. any other person financially dependent on the covered individual; and
    iv. 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.
c. 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.
d. Where a non-UT Southwestern employee or trainee is an employee or trainee of an affiliated hospital or research center that has a separate conflict of

interest program, the non-UT Southwestern employee or trainee must still file a disclosure and, if applicable, a COI Management plan with the IRB. The HRPPD will coordinate with the COI office and with the respective office at the affiliated hospital or research center when necessary

III. Procedure For Policy Implementation

a. Individual COI Management

i. Investigators must self-identify any financial interests for all research personnel on New Protocol Submissions and at Continuing Review. If there has been any change in the financial interest status relating to the research at the time of Continuing Review, the IRB will review financial interests for which the COI Committee has issued a COI management plan (as described below) as part of its continuing review.

ii. If the related Financial Interest is found to be a Significant Financial Interest (as defined by Res-401 Financial Conflicts Of Interest In Research: Disclosure, Management, And Reporting), the HRPPD staff coordinates with the COI Office to ensure that the Financial Interest is considered in light of the protocol and reviewed by the COI Committee to determine how to manage, mitigate or eliminate the potential COI.

1. A recommendation is made by the COI Committee as to the appropriate components of a management plan for that particular protocol but the final determination regarding the management plan is made by the IRB when the study involves human subjects.

2. Based on the significance of the conflict and the potential adverse effects on the protection of subjects, COI management plans can include:

a. Disclosure to research subjects through the consent process;

b. Modifications in the research plan and data analysis plan;

c. Changes of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

d. Monitoring by independent reviewers;

e. Divestiture or reduction of financial interests;

f. Severance of the relationship that create an actual or potential conflict of interest;

g. Appointment of a non-conflicted Principal Investigator or change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

h. Reduction of some or all financial Interests;

i. Severance of the relationships that create an actual or potential COI; or

j. Disallowing the conduct of research (or a portion of) at UT Southwestern.

3. As part of its review process, the Convened IRB (full board) or IRB Designated Reviewer (expedited) will make a determination as to whether the conflict adversely affects the protection of human subjects. Considering the protocol and the approved COI management plan (if applicable), the IRB will determine if subjects are adequately protected

4. The Convened IRB (full board) or IRB Designated Reviewer (expedited) may make any of the following determinations:

a. Approve the COI management plan as written; or

b. Request changes in the COI management plan and conditionally approve the plan with those changes; or

c. Request changes in the COI management plan, and defer review

until a revised plan is received; or

d. An IRB Designated Reviewer may refer the review to the Full Board.

5. Review of COI management plans are documented in the IRB minutes for full board review and in the Ethos protocol file for expedited review. If a conflict of interest exists, final IRB approval should not be given until an approved COI management plan or determination that a management plan is not required from the COI Office or Committee is in place.

iii. If the financial interest is a non-Significant Financial Interest, the HRPPD and IRB will confirm that an appropriate determination from the COI Office or Committee is in place that a management plan is or is not necessary.

iv. Final approval of an initial or continuing review submission will not be granted until:

1. the Principal Investigator and study personnel have completed their annual COI disclosure to the COI office, and

2. the IRB has verified there are no Financial Interests that could affect the protocol, or

3. any Financial Interests that could affect the protocol have had a COI management plan approved by the IRB.

v. A copy of the final, approved COI management plan is stored within the COI system that is integrated with the Ethos system and accessible to the HRPPD, as well as to the COI Office.

vi. If the COI status of an investigator or study personnel changes during the course of a study, the individual is required to notify the HRPPD and the COI Office within 30 days of the change. If the COI now represents a significant financial interest, the Convened IRB (full board) or IRB

Designated Reviewer (expedited) will review the change as a modification to the protocol.

b. Institutional Conflict of Interest Management

i. An institutional conflict of interest ("ICOI") may exist when the financial interests of UT Southwestern or of an institution 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

ii. An institutional financial conflict of interests exists when any of the following might affect the design, conduct, and/or reporting of research:

1. Licensing activities
2. Gifts to UT Southwestern
3. Equity interests
4. Financial interests of senior administrative officials
5. Other financial interests

iii. UT Southwestern has integrated the institutional conflict of interest management program with its existing COI program as described herein.

iv.

v. If an institutional Conflict of Interest is identified, HRPPD staff must coordinate with the COI Office staff to ensure that the financial COI is considered.

vi. The Institutional Official (IO) shall makes the final determination as to whether a UT Southwestern IRB may review the protocol or whether the review should take place at an external IRB.

IV. Definitions

See Glossary Of Human Research Terms

V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

e. RES-401: Financial Conflicts Of Interest In Research: Disclosure, Management, And Reporting

f. ETH-304: Institutional Conflicts Of Interest Policy

g. EMP-158: Outside Activities (Including Outside Employment Or Board Service) Policy

h. ETH-104: Conflicts Of Interest, Conflicts Of Commitment, And Outside Activities

VI. Revision And Review History

a. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB updates to ETHOS

b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

d. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures