UT Southwestern Medical Center

Office of Institutional Compliance and Audit Services

Conflict of Interest Office Assessment

Internal Audit Report SMC25AS0003

April 30, 2025

Executive Summary

The Conflict of Interest (COI) Office at UT Southwestern (UTSW) is dedicated to eliminating or managing potential biases in the design, conduct, or reporting of research, as well as preventing undue influence, and management of activities that may conflict with UTSW's mission. A "Conflict of Interest" or "Conflict of Commitment" (COC) may arise when a UTSW team member has interests or engages in external activities that could influence or appear to influence the individual's ability to conduct objective non-biased research, make objective decisions on behalf of UTSW, or hinder the individual's capacity to perform UTSW job responsibilities. Such conflicts can arise at any time and may involve financial or external activities involving time commitments that could compromise fairness and objectivity. Unaddressed conflicts may damage UTSW's reputation and expose the institution to financial penalties.

The COI Office, located in the Department of Research Regulatory Affairs, is currently charged with performing assessments, supporting management, and performing monitoring of identified conflicts of interest or commitment.

Engagement Results

The Office of Institutional Compliance & Audit Services (OICAS) conducted an audit to assess the design and operation of the processes and controls related to the COI Office. This assessment included a review of the program governance, policies and procedures, and controls supporting the COI and COC cycle (e.g., disclosure, assessment, Committee review, management plan development, and monitoring).

Overall, we recognized multiple strengths for the process(es) including:

- Strong relationship between the COI Office and both the COI Committee and Institutional COI (ICOI) Committee
- The COI Office conducts specialized COI training sessions upon departmental request
- Survey feedback stating the COI Office is personal and employees feel comfortable reaching out for help
- Development and distribution of COI Office tip sheets covering a wide range of topics.

A summary of observations is outlined below:

AREA	OPPORTUNITIES	RISK RATING
Definitions & Risk Tolerance	• Covered Individual Definition Alignment and Risk Tolerance • Significant Financial Interest (SFI) Definition and Risk Tolerance • SFI Appeal Process	**HIGH**
Technology Integration & Optimization	• Integration with Other Information Systems • System Workflows • Automated Identification of Covered Individuals • Manual Inefficiencies Related to SFI and OAR Forms • Committee Review and Management Plan Tracking	**HIGH**
Review Process Efficiency	• Risk-based Review Prioritization Process • Regulatory Alignment of Retrospective Reviews • Linear Review Process • Multiple Formats for Disclosure Submissions • Linkage of Covered Family Members	**HIGH**
Management Action Plans	• Tailored Management Plans • Accountability for Non-Compliance • Management Plan Closure Criteria • Management Plan Monitoring • Interim Management Plans • Review of Precedent	**HIGH**

AREA	OPPORTUNITIES	RISK RATING
Roles & Responsibilities	• Conflict of Commitment Review Obligations • Staff and Faculty Obligations • Enhancements to Committee Resources and Composition	**MEDIUM**
COI Office Operations	• Necessary Assessment Expertise • Key Performance Indicators	**MEDIUM**

Further details are outlined in the Detailed Observations section. Less significant issues were communicated to management.

Management Summary Response

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before July 31, 2026.

Appendix A outlines the objectives, scope, methodology, stakeholder list, and audit team for the engagement.

Appendix B outlines the Risk Rating Classifications and Definitions.

The courtesy and cooperation extended by the personnel in the COI office is appreciated.

Natalie A. Ramello

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April 30, 2025

DETAILED OBSERVATIONS

1. Definitions & Risk Tolerance

Current definitions of covered individuals and significant financial interest reflect low risk tolerance compared to industry standards and peer institutions which increases the population and results in an increased workload for the COI office.

HIGH

1.1 Covered Individual Definition Alignment & Risk Tolerance	Recommendations	Management Action Plan
UTSW's definition of "Covered Individual" exceeds industry standards and those of peer institutions, thereby expanding the statement of financial interest population and placing a greater workload burden on the COI office. UTSW policies, ETH-104 and RES-401 outline the following specific roles in the definition: • "All research study team members" encompasses a wide range of individuals that may not actually participate in the design, conduct, or reporting of research. For example, department administrators, advanced practice providers (APP's), and other clinicians that are not typically involved in research). • Requiring part-time employees (e.g. "regardless of employment status") to disclose all activities for full COI review. This results in certain	Management should: • Evaluate the current risk tolerance related to the definition of "Covered Individual" and therefore the corresponding number of individuals required to complete the annual Statement of Financial Interests. • Review options for excluding categories of individuals that are low risk (e.g., department administrators, APPs, executive assistants) or not in alignment with industry standards for potential removal or revised expectations. Based on risk tolerance, either: • Update the definition of "covered individual"; or • Consider implementing a tiered data collection and assessment approach	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will perform an evaluation of current numbers of individuals in covered categories and review risk tolerance in each area to determine if they can be excluded from the population requiring an annual statement.* *If the definition is not able to be redefined to reduce numbers, management will implement a tiered approach with individuals in lower risk categories having modified requirements and a risk-based prioritization for the review process.*

activities or interests going through duplicative conflict review if those individuals also hold full-time employment elsewhere.	to decrease the administrative burden on the COI office.	
1.2 Significant Financial Interest Definition & Risk Tolerance	**Recommendations**	**Management Action Plan**
UTSW has established a conservative Significant Financial Interest (SFI) of $5,000 based on the PHS SFI threshold. This $5,000 threshold is uniformly applied to all submitted financial interests and management plans are designed around eliminating these relationships without consideration of if the reported interest is subject to NIH requirements. For example, an investigator working on an industry sponsored study that is not associated with federal funding.	Management should consider: • Development of multiple SFI thresholds and allowable compensation, based on the various industry-recognized SFI threshold limits and the processes implemented at peer organizations. • Revising the current assessment process to evaluate each outside interest and the associated disclosed compensation amounts based on the type of interests, relationships, and research involvement disclosed rather than setting an institutional limitation on allowable compensation. Leverage automation logic within InfoEd to support the assessment process. • If SFI limits are changed, review past management conditions, for when compensation has been limited due to a potential conflict of interest to ensure conditions do not unnecessarily	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will review and update the SFI definition based on current PHS and UTS definitions, and in consideration of requirements based on funding source, regulatory requirements, type of interest / relationship and the level of research involvement. The threshold for disclosure will remain at $0.* *Automation logic will be developed in InfoEd, if possible, to support the assessment process based on predetermined decision algorithms.* *Current management plans that were implemented based on the previous limits will be reviewed to determine if they are*

	penalize UTSW investigator and to review and determine if certain management plans are no longer necessary due to the change in SFI limits.	*still required based on any revisions to SFI limits or review processes.*
1.3 SFI Appeal Process	**Recommendations**	**Management Action Plan**
Although investigators can challenge the $5,000 limit through an existing compelling circumstance process, there are no clear quantitative or qualitative guidelines that outline what qualifies as a compelling circumstance. This lack of clear guidance and codified documentation may lead to inconsistencies in approval or denial decisions. The ambiguous nature of this process may result in inappropriate policy deviation approvals, dissatisfaction among employees, and inefficiencies in resource utilization and time management for both the investigator and the COI Office.	Management should consider formalized guidelines that contain both qualitative and quantitative criteria for what constitutes an allowable compelling circumstance within the appeal process. The allowable compelling circumstance criteria should be aligned with any revisions made to UTSW's risk tolerance and SFI thresholds.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 01/31/2026 *Management will:* 1. *Modify the formal appeal process to include requirements for submitting an appeal for challenges to the COI management plan.* 2. *Develop a MP Challenge Form to ensure questions collect adequate information and documentation to support the appeal.* 3. *Develop a criteria checklist for the COI committee to standardize the acceptable circumstances and approval process.*

		4. *Update institution and department policies and procedures to reflect the revised process.* 5. *Consider removing the rebuttable presumption which requires the consideration of compelling circumstances; consider replacing the rebuttable presumption with risk-based review criteria.*

2. Technology Integration and Optimization

The COI office uses InfoEd software to complete and track disclosures. However, there is a lack of integration with other UTSW systems which would allow for increased automation and improved effectiveness and efficiency of processes.

HIGH

2.1 Integration with Other Information Systems	Recommendations	Management Action Plan
The existing InfoEd system lacks integration with other systems resulting in operational inefficiencies. • Human Resources (HR) integration o There is no integration between InfoEd and HR management systems, leading to inconsistencies in reconciling covered individuals and increasing manual data requests between the COI Office and HR. • Grants Management Software Integration	The COI office should, where possible, integrate the InfoEd system with other systems to decrease manual processes and improve effectiveness of review and evaluations. Recommended integrations include: • Collaborate with Human Resources to determine current or establish unique identifiers (other than job codes) to directly integrate the appropriate data from PeopleSoft into InfoEd to support identification of covered	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 07/31/2026 *Management will work with the vendor and other departments to integrate data into InfoEd, where possible, to reduce manual efforts in data entry and research in other systems.*

○ The current integration with grants management software creates obstacles for staff and faculty in disclosing financial interests for new study submissions due to the tedious process (multiple clicks) of reviewing associated sub-funding source information. Only the primary funding source information is prominently displayed. COI Office team members must review funding on multiple screens leading to an increased likelihood of missing all funding sources that should be reviewed and evaluated for potential conflicts. • Open Payments ○ The system does not automatically capture or integrate Open Payments data, therefore this information must be researched and reviewed manually.	individuals. This may be implemented using well-defined job codes or onboarding dates. • Determine any points of integration between the current grants management software (eGrant System) and InfoEd, in particular related to funding sources. Review the current funding source display within InfoEd to determine additional efficiencies that could be gained by a different data display. • Determine if features such as prompts and links for submitting a statement of financial interest into a new study submission system can be implemented to help streamline processes and promote compliance with institutional and regulatory requirements. • Revisit the originally planned integration of InfoEd through the Application Programming Interface (API) made available by Open Payments, as intended during the initial tool implementation, and develop automation or tools to identify discrepancies or items for review.	

2.2 System Workflows	Recommendations	Management Action Plan
Although the system includes a status history that functions as an audit trail, only COI Office staff members have access to key technical capabilities within InfoEd. For instance, when an OAR form is sent to a supervisor for approval, the supervisor cannot mark the approval themselves. Instead, this task must be performed manually by a team member within the COI Office, creating redundancies and a lack of audit trail history (e.g., supervisor approval).	Management should determine if InfoEd capabilities allow all personnel with key roles in the conflicts process to complete and document tasks within the system (i.e., grant supervisors the ability to mark items approved directly within InfoEd and automatically route to the next review step). Management should refine the automation logic to align with its chosen definition of Covered Individuals. This includes identifying job codes, especially in relation to non-clinical personnel, or other unique identifiers to validate a comprehensive capture of individuals required to complete statements of financial interest. Committee and Management Plans: Broaden the usage capabilities of InfoEd to include document management and retention of items that are currently managed manually (e.g., DocuSign for signatures, management plan tracking in Microsoft Excel spreadsheets, RedCap for individual statements, etc.). As part of a future state, consider migrating Committee activities (e.g., documentation, approvals, final management plans) into InfoEd to reduce	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 07/31/2026 *Management will work with InfoEd to update workflows to allow the statement to automatically move to the next step upon supervisor approval of an OA. This will be implemented if the system allows.* *Management will work with InfoEd to explore functionality for creation and management of COI management plans, committee management, and monitoring activities. Where possible, we will implement functionality.*

	the manual nature of the current Committee process. Discrete technological enhancements are provided in *Appendix D*.	
2.3 Automated Identification of Covered Individuals	**Recommendations**	**Management Action Plan**
The automation process for capturing Covered Individuals: • Fails to include non-clinical personnel such as laboratory staff and non-grant-listed researchers (e.g., regulatory coordinators) involved in research design, conduct, and reporting. • Does not differentiate between various roles within research setting; therefore, all covered individuals are subject to the statement of financial interest process regardless of the role they are operating within (e.g., a grant administration role who is not involved in the design, conduct, or reporting of research). • Does not identify individuals with purchasing power over $15,000 who are required to disclose per UTSW policy. COI staff must coordinate with the supply chain department and / or supervisors through a manual validation process to validate accurate	Refine the automation logic to align with any revisions made to the definition of Covered Individuals. This includes identifying job codes, especially in relation to non-clinical personnel, or other unique identifiers to validate a comprehensive capture of individuals required to complete statements of financial interest.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 06/30/2026 *Management will refine the automation logic to align with its chosen definition of Covered Individuals and validate that it is capturing all data correctly. This will include identifying individuals with purchasing power over $15,000 (if feasible), institutional standing committee members, and Institutional Officials.*

identification of these individuals, posing a risk to record accuracy.		
2.4 Manual Inefficiencies related to SFI & OAR Forms	**Recommendations**	**Management Action Plan**
The current procedures for reviewing and assessing SFI and OAR forms are highly reliant on manual processes. Verification of the completeness of statement of financial interests relies on a combination of automated controls (e.g., cannot submit without certain fields completed) and manual review (e.g., review of contract, submission attachments, review of past submitted statements, open payments data). Additionally, there are no automated controls for system-built automation to support comparison of previous year's submissions against the current submission to identify changes or deletion of information. This manual process is time-consuming and prone to inconsistencies, which may compromise the accuracy and reliability of the records.	Work with the vendor to optimize the usage of the InfoEd system to reduce manual efforts. Potential enhancements to consider include but are not limited to: • Optimization of user experience • Data integration and verification • Automated routing and alerts • Centralized database and historical tracking	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will work with the InfoEd vendor to review current configurations and to optimize use of the system. For example, comparing disclosure responses between/within years; ensuring validation is present to ensure statements are completed, etc. If phased implementation is needed for changes a strategic plan / timeline will be developed.*
2.5 Committee Review & Management Plan Tracking	**Recommendations**	**Management Action Plan**
The management plan process is performed and tracked manually utilizing technology such as DocuSign or Excel spreadsheets (e.g., development, management plan signature,	Management should broaden the usage capabilities of InfoEd to include document management and retention of items that are	Action Plan Owner: Jonathan Hunter Action Plan Executive:

monitoring). No part of the management plan process is captured within the InfoEd system, despite the system's capability. No part of the ICOI or COI Committee process is captured or facilitated by the InfoEd system. Committee review packets, minute storage, and approval tracking are all developed and tracked manually. Lack of system usage has contributed to significant manual work and delays in processing tasks related to tracking and communicating items such as committee outcomes, management plans, and outside activity time commitments.	currently managed manually. This could include (but not limited to): • DocuSign for signatures • Management plan tracking • RedCap outcomes for individual statements. Management should consider migrating Committee activities (e.g., documentation, approvals, final management plans) into InfoEd to reduce the manual nature of the current Committee process.	Rhonda Oilepo Due Date: 7/31/2026 *Management will work with InfoEd to explore functionality for creation and management of COI management plans, committee management, and monitoring activities. Where possible, we will implement functionality.*

3. Review Processes Efficiency

Review processes prioritize submission timing over disclosure risk, potentially delaying high-risk reviews depending on submission volume. Manual input, redundant tasks, and minimal procedural documentation are also impacting efficiency and standardization.

HIGH

3.1 Risk-Based Review Prioritization Process	Recommendations	Management Action Plan
Historical practice and current written policy are that all submitted statements, whether submitted through a statement of financial interest or an OAR, must be initially reviewed in order of receipt by the COI office. There is no risk-based review process or triage of disclosures or statements therefore potentially	Management should establish a risk-based conflict assessment framework to support triage and timely assessment of potential active, high-risk conflicts. This risk-based framework should be based on objective criteria that specify various risk factors used to determine the associated risk level (low, medium, and high).	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025

impacted the timely review of active, high-risk conflicts. A recent change has been made to prioritize review of disclosed SFI; however, this has not been codified in policy.	Where possible, leverage automation functionality within InfoEd to automatically triage statements into work queues based on risk level, such that high-risk statements or forms are reviewed prior to those categorized as medium or low risk. Regularly assess the effectiveness of the risk-based review process by tracking metrics such as review times and the accuracy of risk assessments. Any changes to statement assessment and review process should be codified within the appropriate documentation (e.g., procedure, SOP).	*Management will develop a framework / procedure for triage of review based on risk-based criteria and, where possible, will leverage automation functionality within InfoEd to facilitate routing, processing and prioritization of statements.* *Metrics will be tracked and monitored to assess the effectiveness of changes to the process, and for KPIs.*
3.2 Regulatory Alignment of Retrospective Reviews	**Recommendations**	**Management Action Plan**
The historical retrospective review process is not in alignment with regulatory requirements and expectations, particularly PHS retrospective review triggers (e.g., failure to manage a conflict, such as management plan non-compliance, determination that a SFI was not identified or properly disclosed). The current retrospective review process captures all instances of potential non-compliance, which is a larger collection parameter than industry standard and peer institutions and is not aligned with the PHS	Distinguish between the handling of non-compliance and retrospective reviews by creating a separate, formalized process for non-compliance review (refer to *Appendix D* for detailed recommendations regarding establishing a process for non-compliance). Revise the current retrospective review process to align with the NIH definition of retrospective review. When revising the existing retrospective review process, management should consider:	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will revise current policies and procedures to align with regulatory requirements. Revisions will include separate procedures for non-compliance*

policy. Policy (e.g., RES-401) points to conducting retrospective reviews for instances that are not in alignment with regulatory requirements (e.g., challenged management plan decisions). This approach may lead to delays in identifying conflicts that require a retrospective review, appropriate re-management of the conflict, and reporting to appropriate internal stakeholders, external stakeholders, and/or regulatory bodies. The existing processes for identifying conflicts requiring retrospective review: • Rely heavily on manual comparisons of SFI's from previous years or manual investigative work (e.g., review of open payments, review of publications). • Does not have supporting technology or built-in automation to detect potential non-compliance. • Does not have a formalized process / SOP that outlines how the COI Office should conduct a retrospective review, provide retrospective review documentation guidance, or templates, or clearly outlines the required regulatory reporting process. • Does not have a distinct, formalized, non-compliance review process, due to all non-compliance being categorized as a retrospective review.	• Developing standardized retrospective review templates (e.g., mitigation report template, NIH notification letter, corrective action) and checklists to validate consistency and completeness in the review. • Writing a retrospective review process SOP or other appropriate documentation that includes triggers for review, methodology, corrective action examples, reporting requirements, notification protocols, and timelines. • Where possible, InfoEd should be leveraged to identify potential retrospective reviews. For example, automation logic could be used to identify large financial reporting discrepancies between historical statements or identify Open Payment items that are not included in submissions.	*and retrospective reviews. Documentation of procedures will include triggers for review, methodology, corrective action examples, reporting requirements, notification protocols, and timelines.*

3.3 Linear Review Process Flow	Recommendations	Management Action Plan
The current review process is linear and requires two (2) different reviews by the COI Office, therefore causing duplicative work and significant delays. The department is currently broken into three main silos, COC, COI, and management plan ownership therefore creating delays in the review process. The COI Office is consistently unable to review submitted statements and OAR before year end resulting in multiple submissions not being reviewed in time. Submissions that are not reviewed by year-end are automatically denied without any review. • From January through September 2024, a total of 1,639 Statements of Financial Interest were submitted. ○ After excluding statements with a status of "No Interest Reported" or "Request Cancelled," 1,346 (82%) statements required review. • Of the statements that required review, 713 had a status of "No Conflict Identified" or "Conflict Managed," indicating 53% of the reviews had been completed. • Conversely, 633 statements were still "under review," meaning ~47% of the	Management should consider revising the existing linear review process through the following actions: • Establish a process for conflicts of commitment to be reviewed and approved only by the direct supervisor to reduce burden on the COI Office. • For high-risk requests that require both supervisory COC review and COI Office conflict-of-interest review, establish a parallel review approach. This would allow supervisors to review conflicts of commitment while the COI Office performs conflict of interest reviews. Management should consider organizing the department to eliminate “silos”, such that each step of the review for a statement of financial interest by the same staff member.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will:* 1. *Review the current review process and department structure to identify a more streamlined process to decrease duplicative work and delays.* 2. *Define criteria for each review process to ensure disclosures are triaged correctly.* 3. *Update workflow and operating procedures, develop resources, and provide training for impacted individuals (e.g., COI Office staff, supervisors approving OA, etc.).*

statements do not have the review process completed. • 9 of 20 submissions tested with a status of "Under Review" had been pending assessment for an average of 179 calendar days, with the longest pending for 207 days. Automatic denials of submitted requests that were not reviewed within the review period has resulted in non-compliance as the submitters may have already participated in outside activity while awaiting COI Office review and approval.		
3.4 Multiple Formats for Disclosure Submissions	**Recommendations**	**Management Action Plan**
The process for identifying and disclosing conflicts involves both electronic and hardcopy statements (e.g., Redcap), with some hardcopy statements not being uploaded into the InfoEd system. This could lead to gaps in the documentation, inability to develop a holistic view of conflicts, and inability to understand the SFI universe.	Management should utilize the InfoEd system to manage all associated submissions, determinations, management, and tracking so there is a single source of truth. Management should work to eliminate the use of RedCap for retention of historical data. If unable to fully eliminate, establish a process to input all prior data into InfoEd. Consider using automation or Optical Character Recognition (OCR) technology to support the "copy and paste" exercise.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will:* 1. *Update procedures to utilize InfoEd as the source of truth for all submissions, determinations, management and tracking.*

		2. *Review options for minimizing use of RedCap and if possible, migrate all historical data into InfoEd.*
3.5 Linkage of Covered Family Members	**Recommendations**	**Management Action Plan**
UTSW policy requires individuals to disclose interests related to immediate family members; however, there is no process to identify or review covered family members', who have both submitted statements of financial interests to UTSW leading to an inability to validate disclosed information is in alignment. InfoEd does not allow for linkage between UTSW employed family members, resulting in a failure to properly manage conflicts in which activity interest or participation may align with a family member's interest.	Establish protocols for identifying, documenting, and comparing the statement of financial interests of family members that both qualify as covered individuals or when an OAR form is submitted. This should include guidelines on how to assess overlapping interests and participation that could lead to conflicts. As part of this process, consider: • Adding a question within the SFI or OAR form that requests for an individual to disclose if they have an immediate family member who is also a covered individual at UTSW. If "yes", require first and last name fields. • If possible, leverage automation, such as linkage of family members' statements through an identification number, to perform a cross-reference analysis of statement of financial interest information and determine discrepancies within statement of financial interests. • If automation is unable to support family member linkage and cross-reference analysis, establish a manual process to review and compare family	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 7/30/2026 *Management will establish a protocol for identifying, documenting, and comparing the statement of financial interests of family members that both work at UTSW and qualify as covered individuals.*

	member statement of financial interests' information to identify discrepancies or misalignments.	

4. Management Action Plans

There is no risk-based adjustment of management plans, with current practices applying uniform approaches to all cases. Additionally, monitoring and follow-up are insufficient to ensure effective implementation and closure of these plans. A formal procedure is needed to address plan management, including clear criteria for conversion of interim plans, monitoring, and closure.

HIGH

4.1 Tailored Management Plans	Recommendations	Management Action Plan
There is no standardized procedure for independently evaluating study design in relation to financial interests when developing individualized management plans. For instance, a researcher with a financial interest in a sponsor may participate in multiple studies, each with different design, conduct, or reporting requirements, yet there are no specific, tailored management plan conditions. Additionally, if the investigator engages in a new study, with an entity for which a management plan already exists, it is simply considered covered under the existing management plans without formal addition or changes to the management plan. This is due to the generic language in current management	Revise the existing management plan process to independently evaluate conflicts of interest resulting in customized, comprehensive, tailored management plans. When formalizing and enhancing the existing management plan development process, consider the following: • Assessment of risk level • Development of management conditions • Decision trees/guides (Refer to *Appendix E* for additional details)	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 10/31/2025 *Management will revise the current assessment process to consider the SFI in relation to the context of the research activities. The management plans will be tailored to the FCOI for each project. A matrix with examples of interest levels and possible management strategies (dependent on roles) will be included to guide decision making.* *A process will be implemented for re-review of management plans annually*

plans, which states that the plan applies to "all future research." Without customizing management plans based on specific study designs and researcher involvement, there is an increased risk of improperly managing and preventing bias.		*for any required updates (new interest, studies, etc.) or closure.*
4.2 Accountability For Non-Compliance	**Recommendations**	**Management Action Plan**
Interviews revealed that discipline is not applied consistently, and potential disciplinary actions are only mentioned within the 2023 and 2024 Statement of Financial Interest, "Assurances" that disclosers must attest. This attestation states: "discipline, up to and including termination, non-reappointment, or loss of privileges." It was identified during review that: • Disciplinary measures are not clearly outlined within the provided policy or SOP documents nor the annual training document. Current policy states that issues of non-compliance "may subject the covered individual to disciplinary action" and "subject to disciplinary action, up to and including termination of employment" While the annual training says, "Failure to disclose interests accurately, in a timely manner, or in accordance with policy may result in a determination of non-	Management should formally define what constitutes "non-compliance" and should be codified within the appropriate formal documentation (e.g., policy, procedure, SOP). Examples of non-compliance to consider include: • Failure to disclose financial interests • Management plan non-compliance • failure to appropriate and accurately review and approve Conflict of Commitment activity • other unique instances of non-compliance with UTSW COI/COC policy Non-compliance process documentation should be used as the baseline to establish and enforce disciplinary measures. It should include definitions of progressive disciplinary actions and example disciplinary actions associated with non-compliance categories.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 2/28/2026 *Management will revise policies and procedures related to noncompliance to ensure that noncompliance is clearly defined and that disciplinary action references are consistent throughout.* *The noncompliance procedure will include definitions of progressive disciplinary actions, examples of disciplinary actions, and reporting of noncompliance events.*

compliance that may be reported to UTSW leadership and, in some cases, federal agencies." • Disciplinary measures are inconsistently applied and enforced. ○ Several interviewees revealed disciplinary measures are only implemented in cases involving major issues and historically disciplinary exceptions were provided to those in leadership or who bring in a large volume of research. • Retrospective reviews, inclusive of all instances of non-compliance, are currently tracked within RedCap. Although there is a single repository for retrospective reviews, this information is not actively analyzed to determine individuals with repeated non-compliance nor is there a formal validation process to determine that any identified non-compliance has been appropriately remediated.	Develop and provide training for COI Office staff and other relevant personnel on the updated processes for identifying and handling non-compliance. Communication (e.g., training, email, newsletter) on the new non-compliance process, expectations and disciplinary actions should be provided to those that are subject to the requirement. Confirmed non-compliance should be tracked, trended and the data regularly reported (e.g., quarterly, biannually) to appropriate bodies (e.g., UTSW leadership, Committees). Associated disciplinary measures should be cataloged and trended routinely (e.g., biannually) to review consistency in the disciplinary action process. This information should be used to identify systemic issues, training needs, or policy gaps. Furthermore, a formal validation process to review implemented corrective actions associated with substantiated non-compliance should be established and formalized within the appropriate documentation. Management should maintain a separate retrospective review process and continue tracking retrospective reviews. Where possible, synergize the tracking, trending, and reporting between the non-compliance and retrospective review processes.	

4.3 Lack of Management Plan Monitoring	Recommendations	Management Action Plan
The COI Office lacks a formalized, required, risk-based, monitoring process for COI and COC management plan compliance. The current monitoring process relies heavily on voluntary responses from individuals, is a passive, self-statement of financial interest process, and lacks specific evidence requirements and a validation process. Policy identifies a requirement to send out 60-90-day monitoring survey for new management plans and an annual survey of existing management plans; however, interviews and testing revealed this practice is not consistent. • 11 selected samples had an associated management plan that required either a 60-90 day or an annual monitoring plan survey. • Out of these, three (3) samples had a monitoring survey sent, accounting for roughly 27%. • Conversely, eight (8) out of the 11 samples did not have a monitoring survey sent for FY24, accounting for roughly 73%. Furthermore, interviews revealed that Institutional COI management plans are not subjected to the existing monitoring process,	Create a formalized risk-based monitoring framework that prioritizes efforts based on the level of risk associated with each management plan. The risk-based monitoring process should specify monitoring requirements to verify individual's subject to management plans have complied with the conditions specified in the management plan. Higher-risk cases should be subject to more detailed monitoring and compliance validation investigation. Furthermore, consider shifting management plan monitoring responsibilities to supervisors for low risk items or potentially to the regulatory monitoring team for medium and higher risk items and establish a regular cadence for review as this would both reduce burden on the COI Office staff, clarify supervisor responsibilities and ownership in the conflicts process, and ensure the appropriate domain expertise is involved when determining management plan compliance. As part of this process, management should consider: • Codifying within the appropriate documentation that responses to monitoring inquiries related to management plans are required or	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 2/28/2026 *Management will develop a risk-based monitoring process that assigns responsibility for follow up based on the level of risk identified. A standardized procedure will be document that includes requirements for management plan responses, and disciplinary steps for non-compliance.* *The procedures will include a plan for routinely monitoring ICOI management plans for compliance.*

resulting in management plans that lack any associated monitoring activities.	otherwise subject to disciplinary action for non-compliance. • Developing standardized procedures for monitoring compliance with management plans that includes both evidence requirements and validation. • Develop templates or forms to standardize the submission of compliance evidence and promote consistency and completeness. • Leverage InfoEd for the monitoring process with automation where possible. Management should hold Institutional Management Plans to the same monitoring requirements as general management plans. Institutional Management Plans should be reviewed for management plan compliance and then monitored using the standard risk-based monitoring process.	
4.4 Management Plan Closure Criteria	**Recommendations**	**Management Action Plan**
Due to the current practice of adding to existing management plans (see Tailored Management above), it is difficult for management plans to be closed in a timely manner. Additionally, although there are formal management plan closure conditions documented within policy, these conditions often result in management plans remaining	Review UTSW risk tolerance for closure of management plans and enhance the closure criteria in SOP 3.5 to align with the risk appetite. As existing management plans are reviewed, consider both closure of those that are	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 9/30/2025

open long after the potential interest or conflict is no longer relevant or active (e.g., plan must remain active for a minimum of 12 months after study publication).	outdated and broad reconciliation of outdated condition language that prevents closure. For example, current management plan precedent conditions state that management plans must remain in effect until all publications are completed as compared to industry standard of main publication related to the research.	*Management will revise the SOP to include closure criteria and include processes for reviewing open management plans to ensure timely closing.*
4.5 Interim Management Plans	**Recommendations**	**Management Action Plan**
Interviews, documentation review, and testing revealed that while interim management plans are used to address immediate conflict management needs, there are significant delays in the formal review and finalization process. These plans, intended to provide swift responses to urgent situations, often remain open for extended periods or are never converted into a formal management plan. Testing identified two (2) interim management plans signed in March 2023 that had not yet been converted to formal management plans. Additionally, interviews and testing validated there may be instances where the COI Office is unable to obtain management plan approval and signatures from the management plan recipient. This situation limits the authority and oversight capabilities of the COI Office. The lack of timely review and failure to obtain the required signatures may lead to potential	Set specific timelines for the transition from interim to formal management plans. When establishing this process, management should: • Establish a maximum duration for which an interim plan can remain in place before requiring review, finalization, and conversion into a formal management plan. • If migrated into the InfoEd system, consider developing automation logic to identify and notify all involved parties when an interim management plan is approaching the maximum age prior to required conversation to a full management plan. Formally codify in the appropriate documentation that any statement of financial interests related to interim management plans	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 9/30/2025 *Management will revise the SOP to include directives that interim management plans must be sent to the committee promptly to approve conversion to a full management plan. The SOP will include actions to be taken if interim plans are not converted timely.*

non-compliance, policy violations, and necessitate retrospective review and further reporting obligations.	which are not converted timely to full management plans due to actions on behalf of the statement of financial interest submitter may lead to disciplinary actions, up to and including the requirement to divest interests or cease involvement in the requested activities.	
4.6 Review of Management Plan Precedent	**Recommendations**	**Management Action Plan**
While common management plan conditions are stored for precedented language reference, there is no formalized process to review and update these documents nor to review older management plans conditions for consistency with the currently used precedent language	Create a structured process for the routine review of management plan precedent conditions. This process should include: • Routine cadence (e.g., every other year) for reviewing precedent language. • Coordinate with other departments (e.g., Legal, Intellectual Property) as necessary to review and revise precedent language, if needed. Develop a checklist or standardized template for management plans to validate that all necessary elements are consistently included and aligned with current policies.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 9/30/2025 *Management will develop a process for routine review of management plan precedent conditions.*

5. Roles and Responsibilities

Supervisors are unclear regarding the outside activity information provided by the COI office and their roles in the approval process, compounded by incomplete reporting and delegation to administrators unfamiliar with the conflict assessment procedures.

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5.1 Conflict of Commitment Review Obligations	Recommendations	Management Action Plan
Interviews indicated that supervisors are confused regarding both the outside activity information provided by the COI office and their respective roles within the process. Examples include: • Several interviewees cited multiple instances in which supervisors did not have a full understanding of their obligation to not only review the statements but also to approve the activity. Due to the initial review performed by the COI Office COC team, supervisors may already believe the activity has been approved for participation. • Reviews may be delegated to administrators, who do not have the same understanding or familiarity with the conflict process, further compromising the accuracy of the review and approval process.	Management should evaluate and revise the existing conflicts of commitment / outside activity review process and associated roles. Items to consider include: • Revising the review process such that supervisors are solely responsible for the review and approval for outside activity approval. If two layers of review are desired, supervisors and the associated dean could serve as the two layers of review. Requiring supervisors to be responsible for approval will help clarify the supervisor responsibility within the assessment process, reduce burden on the COI Office staff, and align with industry standards. • Revise the supervisor review process to re-incorporate language specifying the requirement for review of permissibility. • If the COI Office does not want to divest their role in the COC process develop risk-based criteria that outlines when a	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 4/30/2026 *Management will:* 1. *Revise the procedures and guidance documentation for supervisor review processes. Updated procedures will include:* • *Acceptable criteria for approval* • *Compliance review process following approval* • *Automated communications* • *Disciplinary steps for supervisors approving non-permissible activities.*

• The current reports provided to supervisors and managers do not provide a complete list of time commitment information. Specifically, the total time spent on activities outside of UTSW is not provided, making it difficult to determine compliance with UTSW policy (e.g. EMP-158 permits up to 8 hours per week (20% of time) on approved outside activities).	COC / outside activity review would require notification to the COI Office staff (e.g., complicated agreement involves foreign activities). Items not meeting the notification requirement to the COI Office should be approved strictly at the supervisor level. • If implemented, leveraging an automated process in InfoEd to automatically route requests to supervisors for approval before the COI Office. • Develop built-in conditions (e.g., time commitment, no use of institutional resources, not a competitor) to guide supervisor review and approval. ○ Where possible, leverage automations within InfoEd to automatically flag requests that are outside the built-in condition parameters. For any implemented changes, management should develop comprehensive supervisor training sessions. Training should provide clear instructions on reviewing and approving activities, clarify the approval hierarchy, and be mandatory annually and easily accessible. Consider holding live, in-person or virtual training sessions during the initial roll out.	2. *Develop comprehensive training for supervisors responsible for the conflict of commitment review process.*

5.2 Staff & Faculty Obligations	Recommendations	Management Action Plan
Interviews indicated that despite existing training and policies, significant confusion regarding the conflict-of-interest statement of financial interest process exists. This uncertainty results in COI staff receiving a high volume of calls and inquiries, limiting the amount of time COI staff can dedicate to conflict assessment and review. Examples include questions on: • What financial holdings must be disclosed in the Annual Statement of Financial Interest form or OAR form. • Requirements associated with both triggers and timeframe for updating a submitted annual Statement of Financial Interest or OAR form. • Additional information required prior to submission approval (e.g., UTSW uniform terms and conditions within any contract). • When someone who is not subject to the annual Statement of Financial Interest is required to disclose.	Management should use audit and survey results to revise training, education and current statements and forms. Enhancements to consider include: • Enhancing COI Office engagement through more personalized new hire onboarding • Implement targeted refresher training and rotating mandatory sessions using COI Office metrics • Enhance COI training with real-world examples and customization based on recent non-compliance situations • Provide examples and instructions in each section to enhance understanding and accuracy of information collection. ○ If supported by InfoEd, add a help section that includes examples for each of the discrete questions within the statement. • Streamline forms and instructions to reduce confusion and errors in submission.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 4/30/2026 *Management will review current training for both new and established employees and update to ensure commonly asked questions are clarified and provide real-world examples based on non-compliance situations.* *Convene focus group to discuss ways to streamline forms and instructions to reduce confusion and errors in submission. Update forms and guidance based on feedback.* *If supported by InfoEd, add a help section that includes examples for each of the discrete questions within the statement.*

5.3 Enhancements to Committee Resources & Composition	Recommendations	Management Action Plan
Current ICOI and COI committees have been designated as advisory committees; however, policy RES-401 outlines the committee's obligation to enforce conflict of interest policies. While there is strong committee engagement, the committee currently does not contain representation from Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Sponsored Programs Administration (SPA) intellectual property expert, leading to insufficient expertise on the Committee. Interviewees and documentation review revealed a lack of training or additional resources and guides (e.g. templated review process, management plan condition guidelines) for committee members to support standardized review of conflicts and management plan decisions.	Develop an ICOI and COI committee charter that clearly outlines roles and responsibilities. The committee charter should align with policy RES-401 and outline the committee's obligation to function as an advisory committee with the responsibility to evaluate conflicts for alignment with policies. Any enforcement should be the responsibility of the Institutional Official. Management should consider including representatives from the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Sponsored Programs Administration (SPA) to expand the range of expertise on the committee and align with peer organizations. Develop tools, such as decision trees or checklists, to guide committee members in determining the need for specific management plan obligations that align with particular outside activities, relationships, or study design. Consider establishing a routine process (e.g., survey) for gathering Committee member feedback that can also be used when there is Committee membership turnover, broad scale changes within the COI Office, or COI Office	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 7/31/2025 *Management will establish a charter for the ICOI and COI committees and develop guidelines for the roles and responsibilities of the committee members.* *COI committee rosters will include representatives from SPA, IRB and IACUC.* *Training will be developed for committee members to ensure conflicts of interest are addressed in a standardized approach and to help implement procedural changes.*

	process. Committee member feedback should be used to facilitate improvements and address any emerging gaps or concerns. Develop a structured training program for committee members held on a routine cadence (e.g., quarterly, biannually). This training program should be aimed at driving consistency in committee member understanding and equipping committee members to remain well-informed and adept at addressing conflicts of interest.	

6. COI office operations

The COI office team is tasked with comprehensive evaluation of all submitted disclosures, encompassing various technical elements, yet may lack domain-specific expertise critical for assessing conflicts effectively. There is also insufficient monitoring of key performance indicators (KPIs) and detailed productivity metrics, which could help identify inefficiencies or imbalanced workloads. Furthermore, insufficient data and context in annual reports and outside activity logs hinder leadership's ability to assess conflicts comprehensively and ensure compliance with policies.

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6.1 Necessary Assessment Expertise	Recommendations	Management Action Plan
Currently the COI office team is responsible for reviewing all aspects of submitted SFI or OAR forms. This includes, but is not limited to, reviewing contracts, licensure, intellectual property, data use agreements, and determining scientific relatedness; however, the COI office staff may not possess domain-specific expertise pertinent to the conflicts assessment.	Management should: • Consider conducting a formal COI office skills and knowledge assessment to identify existing areas of expertise and pinpoint any gaps in domain-specific expertise related to conflicts assessment that may not currently be addressed.	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 7/31/2025

	• Establish a process to actively engage other departments or teams such as Legal, alongside any other relevant parties, such as intellectual property, to collectively assess conflicts, given the subject matter knowledge and domain expertise that resides elsewhere within the organization. • Develop tools, such as decision trees or checklists, to guide COI Office staff in determining the need for additional departmental domain specific reviews based on the content of each statement of financial interest and associated risk. • Codifying within appropriate documentation (e.g., policy, procedure, SOP) the requirement of other departments to participate in the conflict assessment process, including an expected response timeline.	*Management will perform a current state analysis of skills and knowledge of department employees in relation to the various aspects of the review. Management will identify gaps in domain-specific expertise and determine the best approach for addressing these areas when they arise.* *Management will develop a contact matrix and procedures to engage other departments to review submissions when additional expertise is needed.* *Decision trees and guidance will be developed for COI staff to determine when additional input is required and ensure consistency in this approach.*
6.2 Lack of Metrics & Key Performance Indicators	**Recommendations**	**Management Action Plan**
The COI Office Administration does not monitor key performance indicators (KPIs) which could provide leadership insights as to the number or risk level of conflicts identified. Additionally, COI Office leadership does not currently have access to reports containing productivity metrics for COI Office staff, (e.g., number of statements assigned, number of management plans developed) to identify areas for	Management should: • Implement and monitor productivity metrics for COI Office staff (e.g., number of statements processed, management plans developed, and average processing time). • Develop KPIs associated with COI Office productivity metrics, including an	Action Plan Owner: Jonathan Hunter Action Plan Executive: Rhonda Oilepo Due Date: 7/31/2025

improvement, potentially leading to inefficiencies or imbalanced workloads. The annual conflicts report, provided by the COI office to the ICOI Committee, fails to provide meaningful data and context. Additional report data, including enhanced, easily digestible reporting is needed to enable the ICOIC to stay informed on crucial ICOI matters and discharge their advisory duties associated with the annual report period. • For example, there is a section titled "Recipients of ICOI management plans"; however, this only contains the recipient's name, year the management plan was issued, and name of the reported interest. There are no supporting details provided. Additionally, the table within the report does not appear to connect directly with the other report details. The COI Office sends an Outside Activity time log report to supervisors every 6 months and discrete OAR when received. Neither the discrete request(s) nor the 6-month logs report the cumulative outside time commitment. As a result, supervisors must either manually calculate the total time spent on outside activities to determine compliance with UTSW 20% policy or do not perform the additional manual calculation, which may lead to a	automated KPI report. The KPI report should clearly identify KPIs that are below target (e.g., use of indicators for submissions that are past 90 days). • Develop KPIs to monitor disputes to determinations or compelling circumstance submissions and track the number of requests and their outcomes to identify patterns or areas of inconsistency. ○ Use this data to inform policy adjustments and staff training. ICOI Committee Annual Report • Solicit direct feedback from ICOI Committee members on enhancements to the annual report. • Consider providing visual summaries, such as graphs or charts to enhance readability and meaningfulness of the report. Outside Activity Log: • Redesign both the 6-month Outside Activity time log report and the supervisor OAR approval form to include cumulative time commitments across all activity requests, making it easier for supervisors to assess compliance with the 20% policy.	*Management will develop performance reports to ensure goals are met, workload is equitable, and process is efficient.* *Management will review current reports and determine areas where enhancements can be made to improve readability and meaningfulness for committee members and other stakeholders.*

blanket sign-off or failure to identify true total time spent conducting activities outside of UTSW.	• Consider providing visual summaries, such as graphs or charts, that clearly depict total time spent on outside activities, reducing the need for manual calculations.	

Appendix A

Objectives, Scope, and Methodology:

Internal audit assessed the design and operation of the Conflict-of-Interest (COI) and Conflict of Commitment (COC) processes and controls. This assessment included but was not limited to a review of the disclosure, assessment, management, retrospective review, and monitoring processes of conflicts as well as the tools and technology used within the COI Office.

The audit scope period included activities of the COI Office from October 2023 through September 2024. The following areas were reviewed:

- Roles and responsibilities, including oversight and accountability
- System / process configurations
- Policies and procedures
- Assessment of current program against leading practices
- Effectiveness and efficiency of the existing control environment

Our procedures included but were not limited to the following:

- Conducting interviews with key personnel to gain an understanding of the COI and COC processes.
- Review and assessment of relevant organizational policies and other relevant documentation.
- Performed control testing over COI and COC requirements and adherence to stated UTSW policies.

We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' Global Internal Audit Standards™.

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Appendix B

Risk Classifications and Definitions

Each observation has been assigned a risk rating according to the perceived degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management. The following chart is intended to provide information with respect to the applicable definitions, color-coded depictions, and terms utilized as part of our risk ranking process:

Degree of Risk & Priority of Action	
Priority	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of UT Southwestern or the UT System as a whole.
High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to UT Southwestern either as a whole or to a significant college / school / unit level. As such, immediate action is required by management to address the noted concern and reduce risks to the organization.
Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to UT Southwestern either as a whole or to a college / school / unit level. As such, action is needed by management to address the noted concern and reduce the risk to a more desirable level.
Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to UT Southwestern either as a whole or to a college / school / unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact on these risks and controls in ways that this report did not and cannot anticipate.

Appendix C

Key Performance Indicators

The following is a consolidated list of potential key performance indicators (KPIs) for use by the COI Office across various areas:

Office Productivity & Workload		
Indicator	**Purpose**	**Report / Data Fields**
COI Office staff workload volumes	Measure of workload distribution across the various COI office staff members to assess equitable and staff productivity.	Monthly or quarterly productivity report for all COI Office staff members. Report metrics might include: • Total number of statements or forms reviewed • Total number of statements or forms requiring management plans • Number of management plans developed
System & Technology Utilization		
Indicator	**Purpose**	**Report / Data Fields**
Average time spent per disclosure review (pre- and post-automation improvements)	Quantifies efficiency gains from system automation.	Time analysis revealing the amount of time spent by the COI Office related to disclosures review, management plan development, and monitoring.
Percentage of COI-related tasks completed through InfoEd vs. manual tracking	Measures effectiveness of technology enhancements.	Report tracking manual tasks that are migrated into InfoEd to quantify and formally track manual tasks that have been automated.

Process Efficiency & Timeliness		
Indicator	**Purpose**	**Report / Data Fields**
Percentage of reviews pending beyond 90/120/180 days	Flag excessive backlog risks.	Report showing pending reviews and associated timeline.
Total number of SFI & OAR forms submitted by department	Indicate the level of program engagement and awareness among team members within discreate departments.	Report on the total number of submitted SFI and OAR forms broken for each discrete department.
Statement of Financial Disclosure Completion Rate (Annual)	Assess number of identified covered individuals who meet the requirement to complete the annual SFI disclosure.	Percentage of employees or relevant personnel who have completed their COI and COC disclosure within the January-March Annual Campaign.
Statement of Financial Disclosure Compliance Completion and OAR Form Completion (ADHOC)	Measure of how timely employees submit their COI and COC disclosures in accordance with organizational deadlines (30 days of a new study or financial interest).	Total number of ad hoc disclosures received within the review timeframe. Breakdown of the date of ad hoc disclosure vs listed start date of activity / interest.
Time analysis of key components within COI and COC	Assess the responsiveness and efficiency of the program.	Quarterly time analysis report for COI and COC metrics. Report metrics might also include averages of total days from: • Submission to supervisory approval • Submission to COI assessment • COI assessment to COI Committee meeting • Submission to Committee meeting • COI Committee meeting to Management Plan implementation • Submission to final status (e.g., management, no conflict)

Risk-Based Monitoring & Compliance		
Indicator	**Purpose**	**Report / Data Fields**
Percentage of high-risk disclosures	Monitor trends in high-risk cases for potential adjustments to the program and assist in meeting regulatory requirements. Helps to determine that high-risk cases are reviewed timely.	The percentage of COI or COC disclosures that are flagged as high-risk (e.g., significant financial interests, leadership positions in external entities, etc.). Timeline of review associated with high-risk cases.
Total number of conflicts requiring a retrospective review	Identify process failures leading to NIH-reportable violations.	Report of total retrospective reviews performed for the annual time period. Include breakdown of types of compliance issues that lead to retrospective review.
Total number of non-compliance issues	Provide an objective assessment of compliance with UTSW policies.	Report of total non-compliance investigations performed for the annual time period. Report might also include: • Percentage of substantiated issues • Breakdown of associated disciplinary actions taken • Breakdown by department • Identification of repeat offenders • Percentage of non-compliance cases resulting in corrective action • Number of non-compliance cases by category (failure to disclose, failure to follow management plan, etc.)
Percentage of management plans monitored	Measure compliance with monitoring requirements, addressing gaps in plan enforcement.	Report of total monitoring survey / process completed. Report should be broken down by: • Monitoring type (annual, 60 /90 day) • Response received • Response timeline • Appropriate response received

Appendix D

Opportunities for Future Enhancements

1. Statement of Financial Interest Review Process

- Cross train staff across the conflict lifecycle (assessment, management plan, monitoring) to enhance expertise within the COI Office.
- Increase departmental flexibility to address fluctuating volumes of work.

2. Statement of Financial Interest Procedures: Automated Routing and Alerts

- Optimize automated routing procedures to align with a risk-based review process and streamlined simultaneous reviews, ensuring efficient validation of submissions.
- Enhance automated alerts and notifications to remind reviewers of pending tasks and deadlines, maintaining timely processing of submissions.

3. Conflict of Commitment Review Obligations

- Develop built-in conditions (e.g., time commitment, use of institutional resources, non-competition) to guide supervisors during reviews and approvals.
- Leverage automation in InfoEd (where possible) to flag requests outside predefined conditions, such as cumulative time commitments exceeding 20%.

4. Faculty and Staff Obligations

- Streamline forms and instructions to minimize confusion and errors during submission:
    - Consolidate pre-approved activities by clearly listing those activities exempt from statement submissions (e.g., serving on government committees, editorial roles).
    - Provide concise definitions for key terms like "Conflict of Commitment" and "Conflict of Interest."
    - Clarify rules for compensation disclosure and highlight key exceptions, such as activities tied to professional development.
    - Simplify navigation through conditional logic to skip irrelevant sections based on initial responses.
    - Add a "help" section in InfoEd, including examples for specific questions.

5. Attachment Section for Statements

- If supported by InfoEd, include a section with detailed instructions and example screenshots for submitting additional documentation with statements of financial interest.

6. Management Plan Monitoring

- Leverage InfoEd for monitoring processes:
    - Automate triggers for sending surveys related to management plans.
    - Set up email reminders for survey completion and escalate overdue tasks to supervisors or department heads.
    - Use InfoEd as a repository for documentation related to management plans, allowing for survey completion, document uploads, and context sharing.
    - Track monitoring and compliance review results.

7. Financial Interest Threshold

- Use InfoEd to develop and manage compelling circumstances processes (e.g., form completion, committee approval, documentation retention, tracking trends).
- Leverage automation logic within InfoEd to assess statement submissions against multiple SFI thresholds based on research type. For example, flag industry-sponsored studies with compensation exceeding $10,000 for potential conflict assessments.

8. Risk-Based Review

- Leverage InfoEd's automation capabilities to triage statements and forms into work queues by risk level, prioritizing high-risk items for review.
- Regularly evaluate the effectiveness of the risk-based review process using metrics such as review times and accuracy of risk assessments.

9. Integration

- Migrate committee-related activities (documentation, approvals, final management plans) into InfoEd to reduce manual workload.

Appendix E

The following roadmap is provided as a high-level representation of the recommended implementation strategy. While it is informed by the detailed observations and recommendations included in this report, it does not reflect a one-to-one alignment with each individual item. Certain roadmap steps consolidate multiple recommendations or visualize them in a grouped or thematic format for clarity and planning purposes.