



The University of Texas Medical Branch  
Audit Services

Audit Report

Research – Conflicts of Interest

Engagement Number MBG25AS0018

October 2025

The University of Texas Medical Branch  
Audit Services  
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## ***Background***

The Office of Institutional Compliance (OIC) is responsible for monitoring compliance with institutional policies related to outside activities and conflicts of interest (COI). In fulfilling this role, the Conflicts of Interest Office (COI Office) within the OIC provides guidance and support for the submission, review, and management of COI disclosures. Currently, the COI Office is led by the Vice President and Chief Compliance Officer and includes an Associate Vice President of Institutional Compliance, and Compliance Attorney. Under the Research COI policy (IHOP 06.05.01), all researchers are required by federal regulation to annually disclose any actual or potential conflicts of interest—or affirm the absence of such conflicts—and complete COI training specifically for researchers every four years.

Currently, disclosures are submitted through the UT System COI Disclosure Portal. Disclosures are required at the time of an outside activity or if an employee joins the institution as a researcher or otherwise becomes a researcher, and annually thereafter during the Annual Researcher COI Disclosure Period (each January-March). Researchers are also subject to IHOP 06.05.03, which applies regardless of researcher status and requires the submission of an Outside Activity Request necessitating prior approval for certain activities. Each portal submission is reviewed by the OIC to identify the presence of potential conflicts. If the OIC determines that a particular activity poses a conflict, the matter may be escalated to the Conflicts of Interest Committee (COIC) for further evaluation regarding the implementation of potential measures to mitigate and manage the conflict.

The COIC, composed of faculty members and administration, convenes on an ad hoc basis to assess disclosures that present potential, actual, or perceived conflicts. The Committee evaluates associated risks and approves individualized management plans to mitigate conflicts when necessary. Researchers and non-researchers are expected to comply with these management plans to address and minimize risks and ensure transparency. While all disclosures are reviewed by the OIC, the COIC serves as the escalation and review body for matters requiring more detailed oversight management.

In addition to disclosure requirements, researchers must complete Conflicts of Interest training every four years and confirm proper understanding of the requirements of disclosure reporting on conflicts of interest. The OIC actively monitors both disclosure submissions and training completion to ensure the University of Texas Medical Branch (UTMB Health) remains compliant with applicable laws, regulations, and institutional policies.

## ***Objective, Scope, and Methodology***

The audit was conducted to assess the effectiveness of internal controls surrounding the disclosure and management of COI in research activities for the period between September 2023 to July 2025. To achieve this, the following procedures were performed:

- **Policy and Procedures Review** – Evaluated for alignment with best practices based on industry standards and recommendations of the Office of Inspector General.
- **Organizational Structure Assessment** – Reviewed the organizational structure and roles and responsibilities of the COIC for appropriateness and alignment with industry standards.
- **Compliance Monitoring Procedures** – Assessed the OIC’s procedures for managing research conflicts of interest and monitoring compliance.
- **Internal Controls Evaluation** – Evaluated internal controls implemented by the OIC to:
  - Track researchers and verify compliance.
  - Monitor management plans.
  - Assign and track required training completion.
- **Data Analytics and Control Testing**
  - Conducted a comprehensive review of 100% of researchers overseen by the OIC, assessing training completion status using the UTMB Health training database.
  - Applied data analysis to evaluate controls for monitoring researcher disclosures and no-activity reporting.

### *Executive Summary*

The OIC currently provides adequate oversight in reviewing reported disclosures of conflicts of interest and the associated management plans. Existing policies and procedures addressing COI are generally sufficient to meet both institutional and regulatory expectations. The OIC, in coordination with executive leadership, should establish a formal Institutional COIC operating under a defined charter and including representation from clinical, academic, research, and institutional support functions. Such a committee would provide a comprehensive governance structure to oversee and monitor both research and non-research conflicts of interest across the health system, ensuring consistent application of policies and transparent management of risks.

In addition to governance enhancements, opportunities exist to improve the operational effectiveness of the conflict of interest review process. Manual processes used for disclosure review and management could be automated to reduce administrative burden and increase reliability. Integrating disclosure and training data into InfoEd would provide centralized tracking and monitoring capabilities, enabling more effective oversight and streamlined reporting.

### *Detailed Results*

#### **Conflicts of Interest Committee Governance**

The Conflicts of Interest Committee currently meets on an ad hoc basis and does not operate under a formal charter that defines its authority, roles, and responsibilities. Its oversight consists primarily of conflicts of interest involving research employees but encompasses both research

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and non-research conflicts across the institution. The Committee has not been convened since November 2024. The absence of a current formal charter and the lack of regular meetings may reduce the effectiveness of the governance framework for conflict of interest oversight and may limit UTMB Health’s ability to ensure consistent and transparent management of risks across all domains.

**Recommendation 001 High – Conflicts of Interest Committee Governance:**

The Office of Institutional Compliance, in coordination with executive leadership, should establish a formal Institutional Conflicts of Interest Committee operating under a defined charter that clearly sets forth its authority, roles, and responsibilities. The Committee should include representation from clinical, academic, research, and institutional support functions to ensure balanced and comprehensive governance. Establishing this structure would provide oversight of both research and non-research conflicts of interest across UTMB Health, ensuring consistent application of policies, transparent management of risks, and strengthened accountability. The Committee should meet on a regular basis, at least quarterly, maintain detailed records of its deliberations and decisions, and actively contribute to the development and oversight of conflicts of interest training and awareness programs.

**Management’s Response:** The Office of Institutional Compliance plans to consolidate the Conflicts of Interest Committee with the Research Security Council, resulting in a combined committee that would meet every other month and cover both areas, which see significant overlap. Consolidating the Conflicts of Interest and Research Security Council will increase efficiency and decrease duplicative efforts, as well as facilitate communication between the two areas. The merger of these committees will include the addition of institutional support representation and a formal, defined charter that clearly sets forth its authority, roles, and responsibilities.

**Responsible Party:** Vice President and Chief Compliance Officer

**Implementation Date:** April 1, 2026

**Management Plan Supervisor Oversight and Review**

Management plans are drafted by the Office of Institutional Compliance, often based on the determination by the Conflicts of Interest Committee of the appropriate terms for managing and mitigating a conflict or perception thereof, and presented to the researcher who must review and assume accountability by signing the management plan. The review also found that management plans are issued in the form of formal letters signed by both the researcher and the Office of Institutional Compliance. However, the plans do not include the researcher’s supervisors or assign the supervisors accountability for oversight. Currently there is no set process implemented for an employee’s supervisor to have oversight and help with ensuring adherence to the terms of a management plan. Limited monitoring and oversight on behalf of

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the supervisor subjects UTMB Health to the risk of unresolved or unmonitored conflicts of interest.

At present, there are 15 active management plans in place, 12 of which relate specifically to research activities. Once signed by the researcher, these plans take effect and remain active until there is either a change in the researcher's outside activity or interest or the conflict no longer exists (e.g., the researcher is no longer conducting outside activity or no longer has the outside interest). Thus, management plans remain in place for the duration of the conflict. The Conflicts of Interest Office in the Office of Institutional Compliance, checks in with managed individuals periodically to ensure that no changes are needed to the management plans to manage the conflict (e.g., if the terms of the underlying agreement/activity have changed) or whether the conflict no longer exists and thus the management plan can be closed. Management plans are typically revisited only when changes arise that could impact their terms, allowing them to remain in effect for years without formal review or renewal. Regularly scheduled evaluations should be conducted to ensure that management plans remain current, effective, and appropriately aligned with evolving risks.

**Recommendation 002 High – Management Plan Oversight Transparency and Review:**

The Office of Institutional Compliance should establish a periodic review process for all active management plans to confirm their continued relevance and effectiveness. A centralized tracking system should be implemented to monitor renewal dates and prevent lapses in oversight. In addition, management plans should formally incorporate the researcher's supervisors, assigning clear accountability for monitoring compliance and documenting adherence to plan requirements.

**Management's Response:** The Office of Institutional Compliance will implement an annual review process for active management plans, regardless of whether changes have been identified. In addition to an annual review, management plans will continue to be updated anytime changes are identified.

**Responsible Party:** Vice President and Chief Compliance Officer

**Implementation Date:** April 1, 2026

**Research Master List**

The audit confirmed that the Office of Institutional Compliance maintains an internal tracking spreadsheet that is manually updated to record new researchers, disclosure submissions, and completion of required quadrennial conflicts of interest training. This process is highly labor-intensive, requiring significant effort from compliance staff to add or remove individuals, monitor disclosure compliance, and document training completions. Because the process depends on manual entry, it is both inefficient and increases the risk of error. To maintain the Master List,

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staff must consult multiple databases on a daily basis and then manually transfer the information, further elevating the potential for inaccuracies.

Detail testing of the Master List identified the following:

Category	Testing Results
<b>Researchers Not in Taleo Learn</b>	111 of 2,345 researchers were missing from the Taleo Learn report. These discrepancies are attributable to several factors: non-UTMB Health researchers reviewing training content and submitting paper-based attestations; individuals who have separated from UTMB Health but remain on study protocols due to ongoing research activities, including those serving as adjunct professors who no longer complete training through UTMB Learn; and fully separated individuals who are no longer engaged in research but have not been formally removed from the conflict of interest researcher list by the PI.
<b>Separated Researchers</b>	360 researchers listed had since separated from the institution. These individuals continue to be tracked due to the potential for ongoing involvement in research activities following their departure from UTMB Health. This introduces additional complexity in maintaining accurate tracking and oversight.
<b>Training Discrepancies</b>	100 of the 1,874 (5%) active Taleo researchers had variances between the Master List and Taleo Learn report for reported training completion dates. These variances are in part attributable to employees who have separated from UTMB Health but remain on study protocols due to continued research activities. A number of these individuals continue to serve as adjunct professors affiliated with other academic institutions and no longer complete their training requirements through UTMB Learn.
<b>Disclosure Reconciliation Gaps</b>	72 of the researchers (3%) in the Master List could not be matched to the UT System’s All Disclosures, All Requests, or No Activity reports. Of these, 29 were non-UTMB personnel who do not have portal access and are required to disclose conflicts of interest manually.

As the Conflicts of Interest Master List currently serves as the primary tool for monitoring compliance with quadrennial training and annual disclosure requirements, there is a risk that researchers could not be scheduled according to their actual training due dates or that disclosures may be inaccurately recorded, potentially compromising compliance, due to the manual nature of the process. The Office of Institutional Compliance is currently in the process of transitioning its research tracking and disclosure processes by implementing a Conflict of Interest Module in InfoEd, a research administration software platform. Funding for this module was not previously available, necessitating the current manual approach. Implementation of the

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InfoEd Conflict of Interest Module is expected to streamline the onboarding of new researchers, automate the monitoring of disclosure submissions and training completions, and reduce reliance on inefficient manual processes. These improvements are anticipated to enhance both the accuracy and efficiency of conflict of interest oversight.

**Recommendation 003 High – Research Master List:**

The Office of Institutional Compliance should complete its addition of the Conflict of Interest Module into InfoEd and implement it as the primary system for tracking researchers, disclosure submissions, and training compliance.

**Management’s Response:** The Office of Institutional Compliance will proceed with implementation of the InfoEd Conflict of Interest Module which should resolve most of the concerns listed above by automating the conflict of interest disclosure and training requirement monitoring process.

**Responsible Party:** Vice President and Chief Compliance Officer

**Implementation Date:** June 1, 2026

**Research Training Tracking**

Currently, the Office of Institutional Compliance manually assigns researchers their required training in Taleo Learn as they are identified as researchers (e.g., being added to a research protocol) and subsequently notifies them of deadlines through email every four years, as the training comes due. The training timeline is tracked via a formula in the Excel Master List spreadsheet. The implementation of the InfoEd Conflict of Interest Module is expected to streamline this process and largely eliminate the need for manual tracking.

**Recommendation 004 Medium – Research Training Tracking:**

The Office of Institutional Compliance should complete its addition of the Conflict of Interest Module to InfoEd and implement it as the primary system for tracking researchers, disclosure submissions, and tracking training compliance.

**Management’s Response:** The Office of Institutional Compliance will proceed with implementation of the InfoEd Conflict of Interest Module and automating the conflict of interest training monitoring process through the InfoEd Conflict of Interest Module implementation. Furthermore, they will implement communication between InfoEd and Taleo Learn to further automate this process.

**Responsible Party:** Vice President and Chief Compliance Officer

**Implementation Date:** June 1, 2026

## Conclusion

We greatly appreciate the assistance provided by the OIC and hope that the information presented in our report is beneficial.

This audit was conducted in conformance with The Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*. Additionally, we conducted the audit in accordance with the Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions on our audit objectives.

## Observation Ratings

<b>Priority</b>	An issue that, if not addressed timely, has a high probability to directly impact achievement of a strategic or important operational objective of the University or the UT System as a whole.
<b>High</b>	An issue considered to have a medium to high probability of adverse effects to a significant office or business process or to the University as a whole.
<b>Medium</b>	An issue considered to have a low to medium probability of adverse effects to an office or business process or to the University as a whole.
<b>Low</b>	An issue considered to have minimal probability of adverse effects to an office or business process or to the University as a whole.

Report Date:

October 1, 2025

Report Distribution:

To: Tobin Boenig, Vice President and Chief Compliance Officer

Cc: Dr. Jochen Reiser, MD, PhD  
UTMB Health Institutional Audit Committee