

UT Southwestern Medical Center

Conflict of Interest Program Review

Internal Audit Report 16:25

October 11, 2016

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Executive Summary

Background

The University of Texas Southwestern Medical Center (UT Southwestern) administers policies on conflicts of interest (COI), conflicts of commitment, and outside activities intended to provide the guidelines for UT Southwestern employees to act ethically in accordance with the values, applicable laws, rules, and policies of UT Southwestern and The University of Texas System (UT System). Refer to APPENDIX B for a listing of overarching COI policies.

Exempt employees, faculty members, employees and non-employees engaged in research, designated UT Southwestern Committee Members, employees authorized to execute contracts or exercise discretion in awarding contracts or other financial transactions on behalf of UT Southwestern, employees involved in procurement activities and executive officers are required to submit an annual (and within 30 days of acquiring a new financial interest) a Conflict of Interest Disclosure Statement to disclose outside interests. If UT Southwestern employees have outside activities or employment, an electronic Outside Activity Employment (OAE) request is required seeking approval to engage in the outside activity. UT Southwestern reported over 10,600 completed COI disclosures for calendar year 2016 (please refer to APPENDIX C for detailed breakdown).

The Conflicts of Interest Office (COI Office) reporting to the Vice President for Research Administration is responsible for monitoring compliance with UT Southwestern and UT System policies, providing guidance and support in the submission, review, and management of outside activities and conflict of interests. A Conflict of Interest Committee (COI) Committee made up of faculty members appointed by the Institutional COI Officer convenes monthly to review disclosures with a potential, actual or appearance of a conflict and approves applicable management plans to mitigate such conflict. The COI Committee receives ongoing support from the COI Office. All disclosures in electronic form are managed through eResearch, a web based system composed of three sub-systems: eIRB, eCOI, and eOAE. eIRB and is designed for human subject research protocols on-line submissions. COI disclosure roles are maintained in the Robust Identity Management application (RIM) that also functions as the middleware supporting system interface between PeopleSoft HCM and eCOI. A system development and support team reporting to Academic Information Systems (AIS) assists the COI Office with system administration and metrics reporting.

Objectives and Scope

This audit was a UT System requested audit and scheduled as a part of our Fiscal Year 2016 Audit Plan. The overall objectives of this audit engagement were to:

- Assess the program design and oversight as well as effectiveness of COI policies and procedures,
- Review continuous monitoring practices, development of management plans to address internally identified opportunities, communication and reporting practices, and
- Assess compliance with institutional requirements, rules and regulations.

Executive Summary

We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

Conclusion

UT Southwestern policies governing expectations related to conflicts of interest are in line with the requirements provided by UT System policies. The Conflicts of Interest Committee provides adequate oversight in the review of disclosures of conflicts, approval of remedial actions and management plans. The COI and Research Administration Offices provide effective program support and ongoing monitoring for the Medical Center. Opportunities exist to enhance data interfaces into the eCOI system to ensure accurate and correct information is available to monitor incomplete Conflict of Interest disclosures.

UT Southwestern executive leadership and the designated COI Official approved a plan to enhance the program in FY 2017 to implement an Institutional Conflict of Interest Committee (ICOIC). The committee includes external members, oversees monitoring of the UTSW COI program and will review all research and non-research related conflict of interest activities. There were no observations with priority or high risk rating.

The table below summarizes the observations and the respective disposition of these observations within the UT Southwestern Internal Audit risk definition and classification process. See Appendix A for Risk Rating Classifications and Definitions.

Priority (0)	High (0)	Medium (1)	Low (2)	Total (3)
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Improvement opportunities risk-ranked as medium are summarized below.

- **Improve Data Interfaces into the Conflict of Interest Application** – Some eligible exempt and faculty employees were missing a COI statement due to the following: “do not override” (DNO) flag, which prevents updates to the employee’s record; new hires did not receive automated email notification because their system ID was not yet established; possible duplicate accounts were being withheld for additional review; and subsequent personnel status changes that were not reflected in their COI disclosure role.

Research Administration management has implemented or is in the process of implementing corrective action plans. Management responses are presented in the Detailed Observations and Action Plans Matrix (Matrix) section of this report. We would like to thank the Conflict of Interest and Research Administration teams for their assistance and cooperation during this engagement.

Executive Summary

Sincerely,



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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Medium ●</p> <p>1. Improve Data Interfaces into the Conflict of Interest Application</p> <p>Missing or incomplete transfer of role changes from HCM to the COI application resulted in missing COI statements for required employees. The eCOI application relies on complete and accurate data from several sources, including HCM, eIRB and Topaz to create the population of records. Inaccurate or incomplete data from these sources results in incomplete COI disclosures within eCOI.</p> <p>A comparison of qualifying records in HCM to the COI application identified the following data quality opportunities:</p> <p>A. Twelve full-time exempt records were missing a required COI due to the HCM job status change not transferring to the COI application (e.g. hired as PRN & became RN; returning from LOA; terminated & rehired; position transfers; holding a covered primary job and non-covered secondary job; or other factors).</p> <p>B. Two covered faculty positions with manual “Do not Override” or DNO designation in eCOI were missing the disclosure. DNO suspends the generating of a COI template until the DNO flag is removed. AIS Support currently maintains a listing of several hundred DNO records with or without an employee ID number.</p>	<p>A. Collaborate with the AIS Development and Support team to implement COI research profiles for all internal and external accounts required to file a disclosure statement.</p> <p>B. Reestablish parameters in the use of DNO and generate periodic monitoring reports to verify the correct status of these records.</p> <p>C. Obtain periodic reports of potential duplicates for AIS and perform follow up to ensure timely resolution.</p> <p>D. Implement a process that ensures persons’ ID is set up prior to the system welcome and notification of required COI disclosure. Implement periodic reports of accounts without a valid email in RIM and follow up accordingly.</p>	<p>Management Action Plan:</p> <p>A. AIS Support will create a research profile and read-only display to end users in the Click application that displays research associated with that end user, position on research, and any related data. This eCOI system enhancement will include notification of employees when their status has changed which then requires them to submit a COI disclosure. This communication will include a link directly into the eCOI system.</p> <p>B. Clean up effort is underway for users that currently have the Do Not Overwrite option flagged. Users with the Do Not Overwrite option flagged are identified and compared to 2017 system logic. Going forward, DNO records with a status change will be shared with the COI office for review and update.</p> <p>C. We will generate and provide periodic reports of possible duplicate accounts to the COI Office for continuous monitoring no later than the end of January 2017.</p>

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>C. Four possible exempt & faculty duplicates with same first and last names in eCOI were flagged for review by AIS Support. The COI Office does not have system security access to view these possible duplicate records. There are approximately 20 possible duplicates in eCOI.</p> <p>D. Additionally, twelve records had undeliverable email address designation (RIMNOEMAIL@UTSouthwestern.edu) due to newly covered individuals that did not have their UT Southwestern ID established in order to receive the automated welcoming message and notification of required COI disclosure. These undelivered emails bounced back to the COI Office account which disabled any further correspondence with the covered person.</p> <p>In late FY2016, the UT System Regents modified UTS 180 "Conflicts of Interest, Conflicts of Commitment, and Outside Activities" to reduce the reporting requirement for employees who are not authorized to make purchases, decisions or recommendations less than \$15,000. The COI Office and AIS are developing plans to address this updated requirement.</p>		<p>D. A project to substitute the true UTSouthwestern email address in place of RIMNoEmail is currently in production. As new-user profiles with RIMNoEmail are updated systematically with the UTSouthwestern email address, notifications are sent to users at the updated email address asking them to disclose.</p> <p><u>Action Plan Owner:</u></p> <p>A. Through D. - AIS Support</p> <p><u>Target Completion Date:</u></p> <p>A. January 31, 2017 B. November 30, 2016 C. January 31, 2017 D. January 31, 2017</p>

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Low ●</p> <p>2. Reemphasize COI Disclosure Requirements to Covered Persons</p> <p>As of the close of the annual reporting period, June 2016, there were 648 incomplete COI submissions (approximately 5% of total population) in eResearch, and manual review was required by the COI department to identify the various reasons for the incomplete status and then initiate follow up actions.</p> <p>After the manual review was completed, 413 records were identified for data correction and 235 were valid and incomplete.</p> <p>The data correction updates needed will be addressed with the action plans noted in #1 above. For the valid and incomplete records, the top departments contributing to the incomplete status were: Affiliated Hospitals, Internal Medicine, Pediatrics, and Psychiatry.</p> <p>To date, a majority of the incomplete records have been resolved with 38 remained incomplete plus 9 who had their research privileges suspended.</p>	<p>Continue campus-wide education and reemphasize department specific reporting to notify leaders of incomplete COI status records.</p> <p>As needed, reiterate Policy requirements and consequences of COI noncompliance to research study teams.</p>	<p><u>Management Action Plan:</u></p> <p>The COI office will update the department intranet site directly to provide enhanced training to UTSW employees, including updated FAQs to describe conflicts of interest.</p> <p>Work with Principal Investigators to educate employees with incomplete COI disclosures on consequences of noncompliance, including suspension from study team.</p> <p><u>Action Plan Owners:</u></p> <p>COI Office/Research Administration</p> <p><u>Target Completion Dates:</u></p> <p>December 31, 2016</p>

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>Risk Rating: Low ●</p> <p>3. Continue Monitoring of Open Payment Act Reporting</p> <p>The CMS website provides the public with payment information made by manufacturers to individual physicians in accordance with the Physician Open Payments Sunshine Act (OPA). A limited review of CMS reported amounts to UTSW reported amounts indicated some instances where the amount reported to CMS was greater than UTSW reporting.</p> <p>A comparison of UT Southwestern disclosures to CMS for one Clinical Department (3 exceptions out of 10) plus all CMS reported payments to UT Southwestern physicians > \$100k (5 exceptions out of 17), identified some differences. Four of the five included in the > \$100K review were also included in the COI Office review. The underreporting differences ranged from < \$5k to > \$100k.</p> <p>The aforementioned results were consistent with the quarterly monitoring by the COI Office. This process reconciled the Physicians' disclosure from the UT Southwestern database to the CMS website and covered all UTSW disclosures > \$100k plus random sampling of 300 each for those reporting < \$100k or no financial interests. The Q4 2016 review employed statistical sampling of 713 of 1,951 Faculty with M.D. designation, which identified 13 with a variance > \$5k or 1.8% of those tested.</p>	<p>A. Continue educating Faculty Physicians of CMS reported payments and encourage physicians to register with CMS to review and ensure individual financial and consulting relationships are up to date.</p> <p>B. Supplement the current monitoring with reconciliation of CMS reported financial payments to UT Southwestern data for selected top recipients.</p>	<p><u>Management Action Plan:</u></p> <p>A. Enhance department intranet resources to provide timely information to Faculty Physicians.</p> <p>Continue to send targeted communications to Faculty and MSRDP Plan participants.</p> <p>B. The COI Office has implemented this recommendation.</p> <p><u>Action Plan Owners:</u></p> <p>COI Office/Research Administration</p> <p><u>Target Completion Dates:</u></p> <p>A. December 31, 2016 B. Implemented</p>

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
<p>The OPA requires manufacturers of drugs, devices, biologicals, or medical supplies to report annually to CMS certain transfers of value to physicians and teaching hospitals. The purpose of the Act was to raise public awareness and transparency of financial relationships with companies that manufacture or supply medicines or medical devices with physicians. Physicians are encouraged to register with CMS and access its secure website to review and correct information relating to their personal, individual financial or consulting relationships.</p>		

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

Risk Definition - The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	Degree of Risk and 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 a UT institution 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 the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order 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 the UT institution either as a whole or to a college/ school/unit level. As such, action is needed by management in order to address the noted concern and reduce risk to a more desirable level.
	Low	A finding identified by internal audit that is considered to have minimal probability of adverse effects to the UT institution 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 presented on the preceding pages of this report. 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 these risks and controls in ways that this report did not and cannot anticipate.

Appendix B – Institutional and UT System Conflicts of Interest Policies

source: Research Administration internal webpage at <http://www.utsouthwestern.net/intranet/research/research-administration/conflict-of-interest/policies/>

[Financial Conflicts of Interest in Research](#) (COI Policy; RES-401)

[Institutional Conflict of Interest Policy](#)

[Intellectual Property Policy](#)

[Regents' Rules 30103 \(Standards of Conduct\)](#)

[Regents' Rules 30104 \(Conflict of Interest, Conflict of Commitment, and Outside Activities\)](#)

[Relationships of UT Southwestern Faculty, Trainees, and Staff with Those Who Provide Biomedical, Scientific, or Pharmaceutical Goods or Services](#) (Vendor Policy)

Texas Government Code [Chapter 572](#) – Personal Financial Disclosure, Standards of Conduct, and Conflict of Interest

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

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

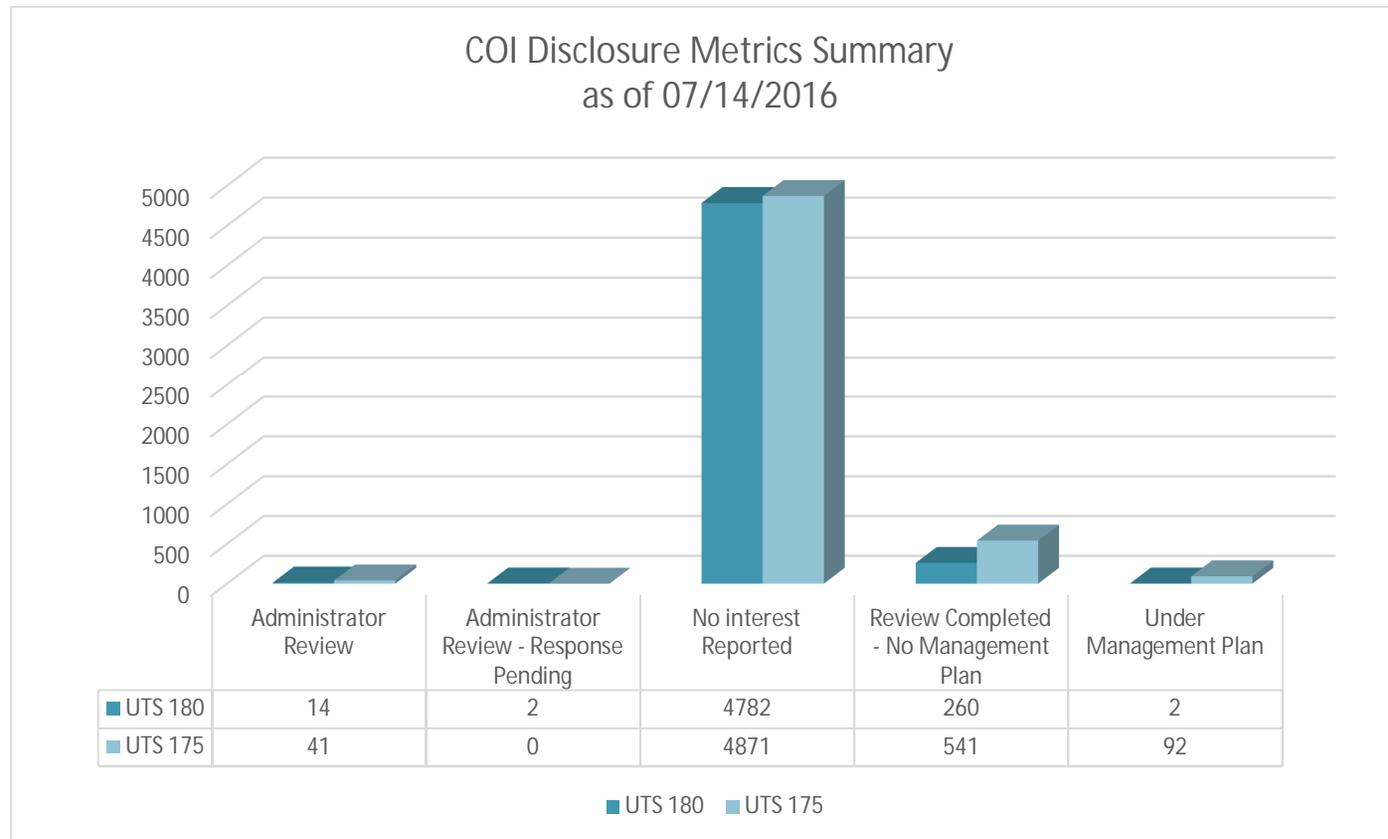
[UTS 134 \(Code of Ethics for Financial Officers and Employees\)](#)

[UTS 175 \(Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research\)](#)

[UTS 180 Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#)

Appendix C – COI Disclosure Metrics for 2016

The graph below provides a snapshot of COI Disclosure Activities and Key Metrics (source: Research Administration):



UTS 175 (Faculty & Research) - 5,545 UTS 180 (Financial Interests) - 5,060 TOTAL COMPLETED – 10,605