



The University of Texas Medical Branch
Audit Services

Audit Report

Conflict of Interest Audit

Engagement Number 2016-025

August 2016

The University of Texas Medical Branch
Audit Services
301 University Boulevard, Suite 4.100
Galveston, Texas 77555-0150

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Background

The University of Texas Medical Branch (UTMB Health) is dedicated to maintaining high standards of excellence, integrity, and accountability in its conduct, whether it involves research activities, clinical practice, institutional decision-making, or engaging in outside activities by its faculty and employees.

Chapter 572 of the Texas Government Code, *Personal Financial Disclosure, Standards of Conduct and Conflict of Interest*, provided the framework from which the University of Texas (UT) Board of Regents (Regents) promulgated various related Regents Rules and UT System (UTS) policies governing the activities of its employees. Additionally, UT System Administration manages a centralized database for reporting identified conflicts of interest or commitment. Based on System guidance, UTMB Health created the following Institutional Handbook of Operating Procedures (IHOP) policies:

- Policy 6.5.1 – *Research Conflicts of Interest*
- Policy 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment and Outside Activities*
- Policy 6.5.4 – *Institutional Conflicts of Interest*

The Conflicts of Interest (COI) Office, a division within the Office of Institutional Compliance, is responsible for administering policy guidelines and monitoring the relationships of institutional employees with outside entities. This includes ensuring all interactions are ethical and do not create conflicts of interest that could compromise patient safety, data integrity, education programs, or the reputation of UTMB Health and its employees.

Insufficient management of conflicts of interest and commitment represents both a reputational and a compliance risk to the institution. In fiscal year (FY) 2015 after implementation of updated policies and practices, Audit Services completed an audit of UTMB's conflict of interest management activities. The UT System Executive Vice Chancellor for Health Affairs requested the health institutions system-wide conduct an audit of conflict of interest as part of the FY 2016 annually-required internal audit hours allocated to the institutional physician practice plans.

Audit Objective, Scope of Work and Methodology

The objective of this audit is to assess the effectiveness of institutional processes used to manage conflicts of interest. The scope of this audit focused on the current COI operations with our methodology including a review of UT System and Institutional policies and procedures; interviews with key personnel; and, review and limited testing of relevant documentation.

The audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing* as promulgated by the Institute of Internal Auditors.

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Audit Results

Audit Services procedures indicate, consistent with the FY 2015 audit results, the UTMB Health COI program appears to be in compliance with UT System rules and policies related to managing conflicts of interest. Audit Services identified opportunities to strengthen current processes and further mature the program.

Design of Policies and Procedures

Audit Services comparison of UTMB Health's COI related policies with applicable Board of Regents Rules and UTS Policies indicated institutional policies contained all key required elements. Additionally, the institutional policies are available via a publicly accessible website as required by UTS 175 and National Institutes of Health (NIH).

Although not required by UT System policies, we noted UTMB Health's policies require regular monitoring by UTMB and/or UT System of financial interest disclosure statements to determine individual and institutional compliance with related policies. Based on COI staff analysis of historic disclosures and trends in healthcare and healthcare industries, physician disclosures represent the highest risk to the institution in the context of conflicts of interest. This analysis lead to the establishment of a monitoring process which compares physician payment data published by the Centers for Medicare and Medicaid Services with UTMB physicians' disclosures to ensure there are no discrepancies.

Prior Approval Requests and Disclosures

Institutional COI policies state that, when possible, employees should submit requests to engage in outside activities no later than 30 days prior to the start date of the activity. Additionally, employees must also disclose certain outside activities and financial interest after acquiring the interest. Activity approvals and disclosures must be reviewed and renewed annually. All approval requests and disclosure information are recorded into a database maintained by UT System Administration. UTMB Health's COI division periodically runs reports from the database to facilitate management of all UTMB related activity.

Appeals Process for Denied Activities

Employees may appeal the finding by the COI Office that a requested activity is not permissible under institutional policies. An employee may also appeal the determination made by his/her supervisor that a permitted activity is denied. Audit Services reviewed the appeals and denial process and determined it was adequate.

Complete and Timely Submission of Requests and Disclosures

Audit Services tested 25 prior approval requests from Fiscal Years (FYs) 2015 and 2016 to ensure the requests were current and submitted within 30 days prior to the start date of activity. All 25 prior approval requests were current; however, 12 of 25 prior approval requests tested were not completed 30 days prior to the start date of the activity; and, 1 of the 25 was not "finalized" as approved in the system.

Additionally, Audit Services tested 75 disclosure forms from FYs 2015 and 2016 for completeness; proper approval; information in the electronic database agrees to the disclosure forms; timely completion; and, forms are current and/or renewed annually. Disclosures

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selected for testing considered a variety of criteria including top researchers reported by Centers for Medicare and Medicaid Services (CMS); number of extramural days used; volume of travel reimbursements; late submission of disclosures; and, executive and external leadership positions. All individuals tested had completed disclosure forms for the current year; however, 39 of 75 forms were not completed within the prescribed timeframes; 3 were missing the start date of the activity; 7 were missing the end date of the activity; and, 2 of the 75 were not “finalized” as approved in the system.

COI Office division personnel indicated a monitoring mechanism has not been established to ensure timely completion or the accuracy of prior approval requests or disclosures submitted.

Recommendation 2016-025-01-PL:

The Chief Compliance Officer should establish an oversight process to ensure the activity reports are reviewed and there is follow up with individuals whose prior approval requests or disclosure forms appear to be overdue.

Management’s Response:

There is no feasible mechanism to ensure that employees to request prior approval 30 days before an activity or to disclose within 30 days of acquiring an interest—OIC is only made aware of these activities/interests when the individual employees complete the online forms. However, with the upcoming implementation of the revised IHOP 6.5.3, OIC will emphasize in training the 30-day requirement. Furthermore, when requests/disclosures are noted to be outside the 30-day window, OIC will use those instances as an opportunity to further educate employees on the requirement.

Implementation Date: Ongoing/immediate

Institutional Disclosure Obligations to the Public

Certain disclosed information must be available on a publicly-accessible and searchable website for the purpose of fostering a transparent environment with regards to conflict of interest and conflict of commitment. NIH’s disclosure obligation requires that institutions ensure public access to disclosed significant financial interests, which are determined to be financial COI, via a publicly accessible website or written response to any requestor, within 5 business days. Audit Services noted that neither UTMB nor UT System maintains a public website providing disclosure information; however, Audit Services validated the current and only research conflict of interest (RCOI) involving federally funded research has been reported by UTMB, and that the COI Office could provide this information within 5 business days of the request in order to meet the NIH’s disclosure obligations.

Institutional Reports to the NIH or Other Public Health Service (PHS) Agencies (when required)

The Code of Federal Regulations (CFR) states that the NIH requires grantees to use the Financial Conflict of Interest (FCOI) module via “eRA Commons” to submit FCOI reports for NIH grants and cooperative agreements subject to the Federal regulation at 42 CFR Part 50 Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS*

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Funding is Sought. Audit Services review of applicable institutional documentation indicated UTMB is in compliance with the grants reporting requirements.

Conflict of Interest Committee

The Conflict of Interest Committee (COIC) plays a key oversight role regarding employee requests for approval or disclosures of activities that may represent a conflict of interest or commitment. The UTMB Health President appoints the Conflict of Interest Official (COIO) who serves as the Committee chair and reports COI activities to the President.

Membership

Institutional policies state the Conflict of Interest Committee shall be comprised of representatives from academic, clinical and basic sciences departments as well as representatives from areas such as Research Services, UTMB's Human Research Protection Program, and Purchasing. Additionally, the Committee must include representatives from the local Galveston County community. Audit Services review of the FYs 2015 and 2016 Committee rosters indicated membership includes representation from all areas as outlined in the policy.

Meeting Documentation

To facilitate discussion during Committee meetings, the COIO appoints a triage team to review and discuss pending disclosures and approval requests. The composition of the team routinely changes based on the expertise needed to ensure an informed discussion.

Audit Services review of the FYs 2015 and 2016 and COIC meeting minutes and interviews with Committee members indicated agendas and associated documentation are distributed timely with sufficient detail to facilitate the discussion of actionable items. Additionally, the COIC decisions appear to be sufficiently documented.

Meeting Frequency and Attendance

The Committee maintains a monthly meeting schedule; however, during FY2015, Audit Services noted 4 of the 12 meetings were cancelled, and during FY2016, 3 of the 9 possible meetings were cancelled due to scheduling conflicts. Additionally, Audit Services analysis of the FYs 2015 and 2016 COIC meeting minutes indicated that for four of the 21 possible meetings, less than 50% of the voting members were in attendance. The COI staff continues to monitor attendance, communicating as necessary with members having poor attendance. Additionally, member attendance is considered by the COIC and the President during the annual appointing process.

Interviews with select COIC members indicated that, overall, the Committee appears to be well-organized and continues to mature as a strategically focused committee. Interviewees also noted a high level of engagement among members along with other positive comments on the process.

Education and Training

Institutional policies related to conflict of interest and conflict of commitment state they must be distributed annually to all employees. A broad spectrum of individuals must complete COI training, including approval authorities; COI Committee members; and, any employee required to disclose and/or receive prior approval under established policies.

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Audit Services review of the FYs 2015 and 2016 COI Office documentation noted COI related education and training materials is available for all UTMB employees. COI Office staff have established a process to ensure training is completed prior to any grant application submissions.

Additionally, Audit Services tested a sample of 25 covered individuals and all COIC members for completion of required training and acknowledgement of related policies. No exceptions were noted.

Oversight and Monitoring

Oversight and monitoring of business processes and controls help provide reasonable assurance that an entity is meeting its stated objectives. Audit Services interviews with the COI Office indicated the COIO meets regularly with UTMB's President to discuss COI program activities. Additionally, the COIO meets with the Senior Vice President and General Counsel on an as-needed basis.

Institutional policies direct the Office of Technology Transfer and the Office of Development to provide quarterly reports to the COIO or his/her designee to facilitate identification of potential conflicts of interest. Audit Services review of the FY2016 quarterly reports indicated that these reports adequately disclose the entities in which UTMB holds equity positions, or from which it has the right to receive royalty payments and monetary gifts, at levels determined by the policy.

Additionally, Audit Services reviewed UTMB's process for monitoring information reported in the Centers for Medicare and Medicaid Services (CMS) Open Payments database and noted adequate controls are in place to reconcile database information with institutionally disclosed information related to significant financial interests of researchers.

Management Plans

Institutional policies require the development and implementation of an individualized plan to manage an employee's conflicts of interest or commitment. The plan shall be in effect within 30 days of the manageable conflict determination made by the COIC.

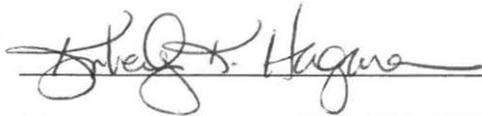
Audit Services review of the 16 management plans currently active indicated they include all applicable information and were appropriately signed, dated, and communicated as required. Additionally, Audit Services noted a monitoring program for ensuring compliance with individual management plans has been established and is functioning as intended.

Conclusion

Audit Services performed an audit of UTMB Health's Conflict of Interest Program. Overall, the program has created an infrastructure addressing the UT System directives related to identification and management of conflicts of interest. Opportunities for enhancement were noted related to the design of policies and procedures and timeliness and monitoring of prior approvals and disclosures.

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We greatly appreciate the assistance provided by the Office of Institutional Compliance staff and hope that the information presented in our report is beneficial.



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