The University of Texas Medical Branch
Audit Services

Audit Report
Conflict of Interest Program Audit
Engagement Number 2015-021
February 2015
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. In January 2013, the Regents established UTS Policy 175, Disclosure of Significant Financial Interests, and Management and Reporting of Financial Conflicts of Interest in Research, and UTS Policy 180, Conflicts of Interest, Conflicts of Commitment, and Outside Activities, to provide more specific guidance related to the identification and management of conflicts. Subsequent amendments to these policies in 2014 included the establishment of a centralized UT System Administration managed database for reporting identified conflicts of interest or commitment.

UTMB’s Conflicts of Interest (COI) Office within the Office of Institutional Compliance (OIC) is responsible for administering policy guidelines and monitoring the relationships of institutional employees with outside entities. This includes ensuring that 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. The COI Office is currently staffed with four employees and the Conflict of Interest Committee Chair serves as the Institutional Conflict of Interest Official.

A well-functioning governance and compliance process is critical in the effective management of conflicts of interest and conflict of commitment activities. Insufficient management of such conflicts represents both a reputational and a compliance risk to the institution.

Audit Objective, Scope of Work and Methodology
The objective of this audit is to assess the institutional processes used to manage conflicts of interest. The scope of this audit focused on the current operations, and the methodology included a review of UT System and institutional policies and procedures; interviews of 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.

Audit Results
Based on the audit procedures performed, UTMB Health’s Conflict of Interest Program appears to be in compliance with UT System rules and policies related to managing conflicts of interest. The following recommended enhancements will help strengthen current processes and continue to mature the program.
Design of Policies and Procedures
Detailed policies and procedures are effective control activities that provide guidance to staff; provide reasonable assurance a department is in compliance with applicable laws and regulations; and, help ensure management directives are followed. Audit Services compared UTMB Health's COI related policies with applicable Board of Regents Rules and UTS Policies, noting our institutional policies appear to encompass the same governance structure and key elements in the UT System policies and rules. Additionally, although not required by UT System, we noted UTMB Health's policies require regular audits by UTMB and/or UT System of financial interest disclosure statements to determine individual and institutional compliance with related policies. Interviews with COI staff indicated these audits have not yet been implemented due to the limited resources available during the operationalizing of the new policies and processes.

Recommendation 2015-021-01-R:
The Chief Compliance Officer should review UTMB Health's policy of regular audits and explore the feasibility of establishing a risk based monitoring process that would provide sufficient oversight of the disclosure process in consideration of the current program staffing model. Alternatively, the Chief Compliance Officer should assess the need for these additional monitoring controls and modify existing policies and practices as needed to provide a sufficient level of oversight.

Management’s Response:
The “Audits” sections of the COI Policies will be changed to “Monitoring” to better reflect the intent of the provision. The COI Office reviews each disclosure and prior approval request as part of their processes, thus ensuring individual and institutional compliance with the policies’ requirements.

Furthermore, both the COI Committee and COI Triage provide an extra degree of oversight regarding higher-risk requests and disclosures, in addition to the oversight provided by the COI Office and Office of Institutional Compliance.

Implementation Date: April 1, 2015

Effectiveness of Policies & Procedures
UTMB Health Institutional Handbook of Operating Procedures (IHOP) policy 6.5.3, Individual Conflicts of Interest, Conflicts of Commitment and Outside Activities, states 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. In addition to receiving prior approval for certain activities, 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 Office receives weekly reports from UT System on all UTMB related activity.
Audit Services tested 25 prior approval requests from fiscal years (FYS) 2014 and 2015 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 the 25 prior approval requests tested were not completed 30 days prior to the start date of the activity.

Additionally, Audit Services tested 50 disclosure forms from FYS 2014 and 2015 for completeness; proper approval; information in the electronic database agrees to the disclosure forms; timely completion; and, forms are current and/or renewed annually. Seventeen of the 50 forms tested were not completed within the prescribed timeframes. COI Office personnel indicated a monitoring mechanism to ensure timely completion is currently not in place.

**Recommendation 2015-021-02-P:**
The Chief Compliance Officer should establish an oversight process to ensure the weekly UT System 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:**
The COI Office will review data from the Outside Activity Portal on a monthly basis to ensure that individuals' COI forms are properly routed for review. The relevant SOPs will be updated to reflect this change. Furthermore, in the case of individuals with overdue COI forms, the COI Office will communicate and work with these individuals to ensure more appropriate compliance in the future.

**Implementation Date:** Effective immediately

**Conflict of Interest Committee**
Interviews with select Conflict of Interest Committee (COIC) members indicated that, overall, the committee appears to be well-organized and continues to mature as a strategically focused committee. Additionally, interviewees noted a high level of engagement among members, positive comments on the process and when solicited, offered suggestions to improve COI operations. The following sections highlight the most prevalent insights and comments received.

**Membership**
IHOP 6.5.3, *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*, states that the UTMB Health President shall appoint the Conflict of Interest Official (COIO), who shall report to the President regarding all COI activities. Upon recommendation from the COIO, the UTMB President shall appoint a COIC comprised of representatives from academic, clinical and basic science 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 FY 2014 and FY 2015 Committee rosters indicated membership includes representation from all areas as outlined in the policy.
Meeting Materials
In addition to the COIC, UTMB Health's COI Program includes a COI triage team. The triage team is comprised of an informal group of COI Committee members who review and discuss pending disclosures and approval requests. The composition of the triage team, set by the COI Official, routinely changes based on the expertise needed to ensure an informed discussion. Summaries of triage meetings are created and maintained in the same manner as the full Committee meeting minutes. Audit Services review of the FY 2014 and FY 2015 triage meeting summaries and COIC meeting minutes and interviews with Committee members indicate agendas and associated documentation are distributed timely and contain sufficient detail to facilitate the discussion of actionable items. Additionally, COIC decisions appear to be sufficiently documented.

Meeting Attendance
The COIC maintains a monthly meeting schedule; however, during FY 2014, Audit Services noted three of the 12 meetings were cancelled due to scheduling conflicts. Audit Services analysis of the FY 2014 and FY 2015 COIC meeting minutes indicated that for six of the 11 meetings less than 50% of the members were in attendance. Upon the recommendation of the COIC Chair, the UTMB President made membership changes for FY 2015 in an effort to improve attendance.

Recommendation 2015-021-03-R:
The Chief Compliance Officer, working with the COIC Chair, should develop and implement a new COI member orientation training process which includes attendance expectations. Additionally, attendance expectations should be communicated to Committee members annually.

Management’s Response:
Pending scheduling, the Provost will attend an upcoming COIC meeting to stress the importance of attendance due to the committee’s important institutional function. The COI Office will also work with the Provost’s Office to develop an additional email communication stressing this point.

Implementation Date: August 31, 2015

Recommendation 2015-021-04-R:
The Chief Compliance Officer, working with the COIC Chair, should continue to monitor COIC meeting attendance and follow up with members with significant absentee rates to ensure their understanding of the importance of their participation.

Management’s Response:
The COI Office will document justifications for members’ absence at COIC meetings. Furthermore, the COIO will address members consistent absences on an individual bases every quarter.

Implementation Date: Effective immediately
Education and Training
IHOP 6.5.3, Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities, requires approval authorities and members of the COIC receive comprehensive training on policies and procedures related to their respective responsibilities. Additionally, training will be available for any employee required to disclose and/or receive prior approval under this policy. This policy as well as other relevant institutional conflicts of interest and conflicts of commitment policies shall be distributed annually to all employees.

IHOP 6.5.1, Research Conflicts of Interest (RCOI), states that each “covered individual” must acknowledge annually that he/she is aware of and has read this policy and is aware of his/her responsibilities regarding disclosure of significant financial interests and of applicable federal and state regulations as well as UTMB and UT System policies, and that training is required for all new researchers, and every 4 years after that for all other researchers, once they have completed it initially. COI Office representatives indicated that all individuals with a RCOI have recently completed updated training due to the new policies effective February 2014.

Audit Services review of the FY 2014 and FY 2015 COI Office documentation noted COI related education and training materials is available for UTMB employees.

Additionally, Audit Services tested a sample of 25 covered individuals and all COIC members for completion of required training and acknowledgement of related policies. Sufficient documentation was available for all covered individuals tested; however, similar documentation was unavailable for the COIC members. COI Office representatives indicated they currently do not maintain comprehensive training records for the Committee.

Recommendation 2015-021-05-P:
Audit Services recommends that the Office of Institutional Compliance maintain supporting documentation that the COIC members responsible for approving and managing outside activities and interests completed their required training.

Management’s Response:
The documentation for COIC members only reflected research training, not a more comprehensive regimen. The COI Office has rectified this for FY 2015 and specifically records COIC members’ training as including the more comprehensive presentation.

Implementation Date: Effective immediately

Management Plans
Institutional policies require the development and implementation of an individualized plan to manage an employee’s conflicts of interest or commitment. A management plan may impose any condition and prescribe any action necessary to manage, reduce, or eliminate a financial conflict of interest to ensure that the employee is free from bias or the appearance of bias when fulfilling his/her institutional duties. The plan shall be in effect within 30 days of the manageable conflict determination made by the COIC.

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Audit Services review of the current 13 management plans currently indicated they appear to include all applicable information and were appropriately signed and dated. However, Audit Services noted two management plans were not referenced in COIC meeting minutes as part of the group’s deliberations.

**Recommendation 2015-021-06-R:**
The COIC Chair should ensure discussion and approval of all management plans is appropriately documented in the Committee meeting minutes.

**Management’s Response:**
An item will be added to the agenda of each COIC meeting for discussion of management plans to be implemented. The COIO will sign these management plans at that time.

**Implementation Date:** Effective immediately

**Monitoring and Reporting**
Monitoring and reporting of personnel, business processes and controls provides reasonable assurance that an entity is meeting its stated objectives. During Audit Services interview with the COIC Chair, he indicated having regular meetings with UTMB’s President to discuss COI program activities. Additionally, the Chair meets with the Senior Vice President and General Counsel on an as-needed basis.

IHOP 6.5.4, *Institutional Conflicts of Interest*, states the Office of Technology Transfer and the Office of Development will provide quarterly reports to the COI Official or his/her designee to facilitate identification of potential conflicts of interest. Interviews with COI Office personnel indicated a quarterly report is not currently received. Additionally, Audit Services noted a monitoring program for ensuring compliance with individual management plans has not been established.

**Recommendation 2015-021-07-R:**
The Chief Compliance Officer should develop and implement a risk-based management plan monitoring process to provide assurance that the affected employees are in compliance with the terms of their respective plans.

**Management’s Response:**
Processes are being developed with the Institutional Office of Regulated Nonclinical Studies for ongoing, biannual analysis and monitoring of certain high-risk research studies that are subject to management plans. All other management plans are reevaluated on an annual basis—per UT System and UTMB policy, all requests and disclosures must be renewed annually. The COI Office performs due diligence on a case-by-case basis that ensures that circumstances have not changed and that the individual is complying with the requirements of the implemented management plan.

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Recommendation 2015-021-08-R:
The Chief Compliance Officer should assess the need for additional monitoring controls such as quarterly reporting from the Office of Technology Transfer and Office of Development, and modify existing policies and practices as needed to provide a sufficient level of oversight.

Management's Response:
The COI Office will work with the Office of Tech Transfer and the Office of Development to establish processes for these quarterly reports.

Implementation Date: September 1, 2015

Conclusion
Audit Services performed an audit of UTMB Health's Conflict of Interest Program. Overall, the relatively new program has created an infrastructure that appears to address the UT System directives related to identification and management of conflicts of interest. Opportunities for enhancement were noted related to policies and procedures; maintaining training and Conflict of Interest Committee documentation; Committee attendance; and, oversight and monitoring.

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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