October 17, 2016

Andrea Giuffrida, Ph.D.
Vice President for Research
UT-Health Science Center- San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78229-3900

Dear Dr. Giuffrida:

The University of Texas (UT) System Audit Office has completed its audit to determine whether The UT Health Science Center at San Antonio (UTHSCSA) has a program in place to identify, monitor, disclose, and manage research conflicts of interest (COI), and whether the program is effective. The scope of the audit included the period from September 1, 2014 through December 31, 2015.

During the course of our work, we became aware of other opportunities to strengthen controls related to identification, monitoring, and management of COI. While not all reported information is research specific, we have included recommendations in the attached report for management to consider that addresses research and non-research related COI.

We conducted our audit in accordance with The Institute of Internal Auditors’ *International Standards for the Professional Practice of Internal Auditing*.

We appreciate the assistance provided by UTHSCSA’s management and personnel.

Sincerely,

J. Michael Peppers, CPA, CIA, QIAL, CRMA
Chief Audit Executive

cc: Michael E. Black, Senior Executive Vice President and Chief Operating Officer, UTHSCSA
Joseph O. Schmelz, Ph.D., Assistant Vice President for Research Administration, UTHSCSA
Angela D’Anna, CIA, CISA, CFE, CHC, Chief Audit Executive, Internal Audit & Consulting Services, UTHSCSA
The University of Texas System Administration
Conflict of Interest Process Audit Report
FY 2016

October 2016

THE UNIVERSITY OF TEXAS SYSTEM AUDIT OFFICE
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EXECUTIVE SUMMARY

In January 2013, The University of Texas (UT) System established UTS175, Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research (UTS175). The purpose of UTS175 is “to promote objectivity in research by requiring institutions to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from researcher financial conflicts of interest.” UTS175 requires each institution “to adopt standards for the disclosure, management, and reporting of individual financial conflicts of interest in research that go beyond the requirements of the federal regulation.” In addition, UTS175 is applicable to all “externally-funded research, regardless of the funding source, as well as to research that does not have external funding.”

The overall objective of this audit was to determine whether the UT Health Science Center at San Antonio (UTHSCSA) has a program in place to identify, monitor, disclose, and manage research conflicts of interest (COI), and whether the program is effective. The scope of the audit included the period from September 1, 2014 through December 31, 2015. During fiscal year (FY) 2016, UTHSCSA’s internal audit function was in process of obtaining additional audit resources. The UT System Audit Office performed this engagement to assist UTHSCSA complete a risk-based audit from its FY 2016 audit plan.

UTHSCSA’s Conflict of Interest Committee (COIC) is responsible for providing oversight of the institution’s management of the COI program, including both research and non-research related COI. Consequently, the scope of our work included determining whether opportunities existed to strengthen the identification, monitoring and management of COI that was not always research specific.

RESULTS SUMMARY

This COIC is generally meeting monthly and has focused its efforts on managing, reducing, resolving, or eliminating identified conflicts of interest that could impact externally-funded research. The COIC is supported by the COI office that is comprised of the assistant vice president for research operations and the COI manager. The COI office is responsible for organizing and facilitating the COIC meetings, managing the annual institutional disclosures process, providing in-person campus-wide training, coordinating with Office of Sponsored Projects (OSP) and the Institutional Review Board (IRB) to identify potential COI that could have a direct impact on research, and facilitating management of confirmed conflicts of interest. To facilitate UTHSCSA’s COI program, management has developed an application called iDisclose. This system is used to meet the disclosure requirements for UTS175 and UTS180, Conflicts of Interest, Conflicts of Commitment, and Outside Activities (UTS180), has enabled the institution to transition from a paper-based manual system to a digital one, can be used to facilitate public information requests and reporting requirements of external sponsors, and is used to review reported COI.

From the work we performed, we determined that the COIC monitors the development and implementation of the management plans and that the COI office facilitates this process. The executed management plans indicate several levels of review and approval and outline the roles and responsibilities of conflicted researchers. While management has several controls in place to identify and manage disclosed COI that could impact research, we became aware of other opportunities to strengthen controls related to identification, monitoring, and management of COI, which included COI that was not research specific. From the work we performed, we identified one
Priority finding that addresses both research and non-research related COI:

1. We identified 56 faculty members with active research awards and 60 post-doctoral students that did not complete required annual financial interest disclosures for calendar year (CY) 2015. However, completion of annual disclosures was not limited to UTHSCSA employees involved in research. In total, 789 employees (including 334 faculty members and 33 administrative & professional employees) did not complete their annual financial interest disclosures as requested. Currently, sufficient controls are not in place to ensure that disclosures are completed within iDisclose after the reporting period ends, and there is insufficient follow-up with employees who have not completed their disclosures.

In addition to the observation above, we identified four high-level findings as described below:

2. The COIC and the COI office’s attention to identifying and managing reported conflicts of interest that could impact externally-funded research is appropriate; however, this emphasis does not cover the entire scope of COIC responsibilities, which includes COI that could impact the procurement process and patient care.

3. We identified 23 individuals engaged in outside activities where no evidence of prior approval was obtained. Of these, seven participated in outside activities that were not disclosed in CY 2015.

4. The annual disclosure process is based on what faculty and staff members disclose, and management is relying on them for the accuracy and completeness of disclosures made. The COI office reviews disclosures to determine if it overlaps with a faculty member’s research. However, some disclosures reviewed appeared incomplete, and there is no process in place to validate the accuracy and completeness of disclosures made.

5. Management uses its Knowledge Center application system to automatically notify new employees of compliance training requirements, including COI training. 25 of 30 new employees tested did not complete COI training. At some point, the Knowledge Center notifications had been disabled and there were not sufficient controls in place to ensure that all covered individuals completed COI training.

RECOMMENDATION SUMMARY

While not all reported information is research specific, we have included recommendations in the attached report for management to consider that addresses research and non-research related COI. To address the observations described above, we have recommended that management:

1. Develop a process, in coordination with the schools and departments, to ensure that all required employees complete their annual disclosures. In addition, the COI office should provide a status report of annual reporting process to the COIC, which can ensure corrective action is taken.

2. Develop a process to identify activities reported in the annual disclosures that require prior approval but did not receive such approval. Identified instances of non-compliance should be forwarded to the affected deans and communicated to the COIC. Additionally, regular updates should be provided to the COIC on follow-up progress.

3. Develop an appropriate governance and oversight structure to include institutional oversight for non-research related COI.

4. Develop a risk-based process to validate whether disclosures made are complete and reasonably accurate and update the COIC on the results of this process.

5. Develop and implement procedures to ensure that covered individuals are completing COI training and update the COIC on monitoring results to ensure that all covered individuals complete required training.

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1 A Priority Finding is defined as an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole. Non-Priority Findings are ranked as High, Medium, or Low, with the level of significance based on an assessment of applicable Qualitative, Operational Control, and Quantitative risk factors and probability of a negative outcome occurring if the risk is not adequately mitigated.
CONCLUSION
Opportunities exist to strengthen controls and monitoring related to the annual disclosure process, the prior approval process, completeness and timeliness of disclosures, and COI training. Opportunities also exist to strengthen institutional oversight of non-research related COI, which could impact the procurement process and patient care. In addition, the results of monitoring of activities should be reported to the COIC, which could facilitate corrective action when needed. Because the report recommendations address both research and non-research related COI, executive management will need to determine the appropriate individuals and/or functional areas that will be responsible for addressing the recommendations.

J. Michael Peppers, CPA, CIA, QIAL, CRMA
Chief Audit Executive

Eric J. Polanski, CPA, CIA
Director of Audit
BACKGROUND
To address the increasing complexities of the financial interests held by researchers and the resulting interactions among government, research institutions, and the private sector, the Public Health Service and the Office of the Secretary of the U.S. Department of Health and Human Services revised, in 2011, the Financial Conflict of Interest (FCOI) regulations that had been previously published in 1995. The purpose of the 2011 revisions was to increase accountability, add transparency, enhance institutional management of researcher FCOI, strengthen oversight by the National Institutes for Health (NIH), and promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and contracts will be free from bias resulting from researcher FCOI.

In January 2013, The University of Texas (UT) established UTS175, Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research (UTS175). Consistent with the revised FCOI regulations, the purpose of UTS175 is “to promote objectivity in research by requiring institutions to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from researcher financial conflicts of interest.” UTS175 requires each institution “to adopt standards for the disclosure, management, and reporting of individual financial conflicts of interest in research that go beyond the requirements of the federal regulation.” In addition, UTS175 is applicable to all “externally-funded research, regardless of the funding source, as well as to research that does not have external funding.”

During fiscal year (FY) 2016, UT Health Science Center at San Antonio’s (UTHSCSA) internal audit function was in process of obtaining additional audit resources. The UT System Audit Office performed this engagement to assist UTHSCSA complete a risk-based audit from its FY 2016 audit plan.

AUDIT OBJECTIVES
The overall objective of the audit was to determine whether UTHSCSA has a program in place to identify, monitor, disclose and manage research conflicts of interest (COI) and whether the program is effective. Because UTHSCSA’s Conflict of Interest Committee (COIC) is responsible for providing oversight of the institution’s management of the COI program, which includes research and non-research related COI, our audit objective also included determining whether opportunities existed to strengthen the identification, monitoring and management of COI that was not always research specific.

SCOPE & METHODOLOGY
The scope of the audit included the period from September 1, 2014 through December 31, 2015. To achieve our objective, we conducted interviews with institutional and UT System personnel, gained an understanding of applicable polices, examined annual disclosures and other information for a sample of UTHSCSA employees, reviewed COI management plans, and performed other procedures deemed necessary to complete our work.

Our audit was conducted in accordance with the guidelines set forth in The Institute of Internal Auditors’ International Standards for the Professional Practice of Internal Auditing.

CRITERIA
- Regents’ Rules and Regulations, Rule 30104 – Conflict of Interest, Conflict of Commitment, and Outside Activities
- Regents’ Rules and Regulations, Rule 90101 – Intellectual Property
• UTS175, Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research
• UTHSCSA policies and procedures:
  o Handbook of Operating Procedures (HOP) 1.6.11, Conflict of Interest Committee
  o HOP 10.1.6, Conflicts of Interest in Scholarly, Research, and Clinical Activity
  o HOP 10.1.9, Conflict of Interest, Conflict of Commitment and Outside Activities
  o HOP 10.1.12, Institutional Conflict of Interest Policy

**ENGAGEMENT RESULTS**

UTHSCSA’s Conflict of Interest Committee (COIC) is responsible for providing oversight of the institution’s management of COI. We reviewed the COIC meeting minutes and determined that the COIC is generally meeting monthly and has focused its efforts on, managing, reducing, resolving, or eliminating identified conflicts of interest that could impact externally-funded research. We interviewed a sample of COIC members and those interviewed appear to understand their role and responsibilities. We also validated that the committee’s membership is in compliance with the requirements of HOP Policy 1.6.11, Conflict of Interest Committee.

The COIC is supported by the COI office that is comprised of the assistant vice president for research operations and the COI manager. The COI office is responsible for organizing and facilitating the COIC meetings, managing the disclosures of outside activities that occur each year, providing in-person campus-wide training, coordinating with the Office of Sponsored Projects (OSP) and the Institutional Review Board (IRB) to identify potential COI that could have a direct impact on research and to manage identified COIs.

The requirements of UTHSCSA’s COI program as well as key roles and responsibilities of the COIC and the COI office is documented in institutional policies. Section 3 of UTS175 requires that each institution “adopt a policy for the disclosure, management, and reporting of individual financial conflicts of interest in research. To satisfy this requirement, the institution may, but is not required to, adopt the model policy applicable to its institution.” We compared the UT System Model Policy for Health Institutions to UTHSCSA’s COI policies and determined that UTHSCSA has adopted model policy requirements. As required by UTS175, UTHSCSA has incorporated its COI policies into the institutional HOP. These policies are available to employees and the public on the institution’s publicly accessible website.

To facilitate management of the COI program, management has developed an application called iDisclose. This system is used by faculty and exempt staff to report outside activities and, as of November 2015, is used by employees to seek prior approval to participate in outside activities where such approval is required by policy. Those interviewed indicated that the iDisclose has made the disclosure process far simpler and efficient. The iDisclose system has allowed UTHSCSA to transition from a labor-intensive, manual process to a digital one. The system is also used to meet the disclosure requirements for UTS175 and UTS180, Conflicts of Interest, Conflicts of Commitment, and Outside Activities (UTS180), reducing the need for researchers and those directly involved in research from making two separate annual disclosures. The iDisclose system also provides a single portal to capture information used to fulfill several administrative and reporting needs, which includes reporting to the external agencies and responding to public information requests. If requested, UTHSCSA has five business days from the date the receipt of a request to provide the requested information. The COI office has a process in place to meet the NIH’s disclosure obligation, and we validated that the COI manager completed the required NIH disclosures for applicable faculty. In addition, the COI manager notifies OSP of any researcher that has a conflict that is being managed or requires management.
From the work we performed, we determined that the COIC monitors the development and implementation of the management plans and that the COI office facilitates this process. The executed management plans demonstrate several levels of review and outline the roles and responsibilities of the conflicted researcher. An additional level of review is required for intellectual property owned by the UT System Board of Regents. Such management plans are also reviewed and approved by the UT System Office of General Counsel and the Executive Vice Chancellor for Health Affairs. The IRB must also review management plans involving human subject research and can add additional controls to a management plan. The deans approve the management plans as well and may add additional requirements to manage an identified COI. The COI manager has begun using a system called REDCap to obtain annual updates from researchers with management plans. The system allows progress reports to be tracked digitally and to identify when an update on a management plan is due from faculty.

While management has several controls in place to identify and manage disclosed COI that could impact research, opportunities exist to strengthen the existing program. Because observations and recommendations that follow address both research and non-research related COI, executive management will need to determine the appropriate individuals and/or functional areas that will be responsible for addressing the recommendations.

The Annual Disclosure of Financial Interests Process
At UTHSCSA, the iDisclose system provides a mechanism to complete annual disclosures in accordance with the requirements of UTS175 and UTS180. The institutional equivalent policies that incorporate UTS175 and UTS180 are HOP 10.1.6, Conflicts of Interest in Research and Disclosure, and HOP 10.1.9, Outside Activities, Required Disclosures. Both policies describe who must complete annual disclosures. With a respect to research, the definition of a covered employee is more specific. As defined by HOP 10.1.6, a covered employee is “an individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal researcher, associate researcher, or project director, must file and update financial disclosure statements under this policy.” According to HOP 10.1.9, “all covered employees and research employees are required to disclose outside activities and financial interests through the disclosure process...using the iDisclose application” Covered employees, who are not covered research employees, include: exempt employees and non-exempt employees who are authorized to execute contracts, or who because of their job duties, have authority to exercise discretion with regard to the award of contracts or other financial transactions.

Missing Disclosures
UTHSCSA casts a wide net for annual disclosures. In general, all exempt employees, as recorded in UTHSCSA’s human resource system (PeopleSoft HCM) are requested to make an annual disclosure. This means that there can be employees that do not meet the elements of a “covered employee” that are asked to disclose. An analysis is not done to determine which employees are required to disclose (i.e., meet the definition of a covered individual). Such a process could be labor intensive, subject to error, and employees that have nothing to report have the option to make that disclosure, which appears relatively easy to do in iDisclose. For CY 2015, over 3,000 individuals were requested to complete a disclosure.

Employees are to report outside activities on a calendar year basis and have from January to March of the following calendar year to complete their disclosures. The iDisclose system sends emails to employees reminding them to complete their annual disclosures during the reporting period. By the end of March, the reporting functionality in iDisclose is disabled and employees cannot complete a disclosure without the intervention of the COI office.

Information obtained from iDisclose indicated that 789 UTHSCSA employees did not complete their annual disclosures. Employees likely to have reportable outside activities include faculty and administrative and professional (A&P) employees. Of the 789 employees that did not complete disclosures, 334 (42%) were
classified as faculty members and 33 (4%) as A&P employees. In addition, there were 60 (8%) employees classified as fellows. These can include post-doctoral students that can be engaged in research activities.

We compared the 334 faculty that did not complete CY 2015 disclosures to a listing of faculty with active research awards. From this comparison we found that:

- 56 faculty members with active awards did not complete their annual disclosures.
- Of these 56 individuals, 22 have active NIH awards.

We followed up with the COi manager about most of these faculty members. Four were no longer UTHSCSA employees and during the audit, the COi manager was assisting one faculty member in completing a disclosure. However, the COi manager also confirmed that one faculty member had not completed an annual disclosure for the past three years while another had not completed annual disclosures for the last two.

Annual Acknowledgment
HOP 10.1.6 requires that each covered individual must acknowledge annually that he/she has read and is aware of his/her responsibilities regarding disclosure of significant financial interests and of applicable federal regulations. This is accomplished when an employee completes the certification of acknowledgement of his/her responsibilities as part of the annual disclosure process. An annual disclosure is not considered to be completed until the employee finishes the certification. Consequently, several covered individuals have not completed the annual acknowledgement, as required by policy.

Overall, it appears that sufficient controls are not in place to ensure that disclosures are completed within iDisclose after the reporting period ends, and there is insufficient follow-up with employees who have not completed their disclosures. While HOP 10.1.6 includes consequences for non-compliance, HOP 10.1.9, which is applicable to all employees as defined by the policy, does not include any provision for non-compliance. Non-disclosures by covered employees increase the risk that such employees are engaged in outside activities that create a conflict of interest with sponsored research or other institutional activities.

The observation described above is considered a priority-level finding in accordance with UT System’s Internal Audit finding classification system.

Recommendation: The responsibility for ensuring that covered employees complete required annual disclosures is shared among various functional areas including the UTHSCSA schools and departments, the COI office, and the COIC. To this end, we recommend the following:

- Management should ensure that the 789 employees complete their CY 2015 disclosures.
- Management should develop a process to follow-up with the affected schools and departments to ensure that all required employees complete their annual disclosures, and management from the schools and departments should work directly with the affected faculty and staff to ensure the annual disclosures are completed.
- The COI office should provide a status report of the annual reporting process to the COIC. The status could include the number who have disclosed, the number that have not disclosed, the number that have not disclosed that are researchers and other employees directly engaged on an active award, the affected schools and departments, and other information that could assist the COIC in determining what corrective action it could facilitate.
- HOP 10.1.9 should be updated to clearly include consequences for non-disclosure.
- Management should develop an escalation process in working with faculty and staff that have not completed disclosures.

Management’s Response:

1. Current state:
a. Management has a process in place to engage schools throughout the annual reporting process. Prior to reporting season, each department is asked to provide or confirm a designated department go-to to assist in local efforts to manage the annual reporting process including, but not limited to, reminding their departmental faculty and staff to fulfill their reporting obligations. iDisclose gives go-to’s and Department Chairs the ability to monitor the reporting progress of their employees and review the submitted reports. Prior to the close of annual reporting season, go-to’s are notified again of those individuals who have yet to report. Following the reporting season, a list of all outstanding reports is available to both go-to’s and department chairs.

b. For CY2015, the majority of the 789 employees have either completed the report or left the university. The names of the remaining employees who have not completed the report will be provided to the applicable Executive Committee (EC) member (Dean/VP). The EC member will be responsible to resolve all non-disclosures.

2. Future State:
   a. At the end of the annual reporting period, the COI Office will escalate the issue of non-disclosure to the appropriate Executive Committee member (Dean/VP). The EC member will be given a deadline for certifying completion of the report.
   b. Annual reporting statistics and status of corrective actions by the EC members will be reported to the Conflict of Interest Committee until the issue is closed.
   c. HOP 10.1.9 will be updated to include consequences for non-disclosure.

Anticipated Implementation Date:
1. Certification of completion of the CY2015 reports will be completed by the EC member not later than December 1, 2016.
2. Revision of HOP 10.1.9 will be completed not later than March 31, 2017.
3. Implementation of a process to escalate non-disclosure to the EC member and COIC will be completed not later than March 31, 2017.

Accuracy and Completeness of Disclosures Made
As part of our work, we selected a judgmental sample of 30 faculty members with active research to test various attributes, including whether disclosures made by these individuals were complete. We also selected a judgmental sample of seven institutional leaders to determine whether disclosures made by such individuals appeared reasonably complete and accurate.

For the sample, we performed internet searches to determine whether there were other outside activities for which disclosures could have been made to UTHSCSA. We also compared information reported by third parties to Centers for Medicare & Medicaid Services (CMS) to disclosures for individuals in the sample. The Affordable Care Act requires CMS to collect information from applicable manufacturers (e.g., pharmaceutical companies and medical device companies) and group purchasing organizations in order to report information about their financial relationships with physicians and hospitals and is available on CMS’s open payments website. From the sample of 30 employees, it appears that 10 disclosures were not complete. For some disclosures it appears that travel, lodging, and/or food reimbursed to or directly paid on behalf of the individual was not always disclosed with the associated outside activity that took place in other cities, states or countries.

https://www.cms.gov/openpayments/
The latest data available from CMS during the audit was for CY 2014. From our comparison, we also identified 13 instances where for-profit companies reported compensation, reimbursements, or in-kind amounts for consulting, lectures, honoraria, training, travel, food and beverages for UTHSCSA employees. We compared this information to the disclosures provided by UTHSCSA to UT System’s Office of Strategic Initiatives for CY 2014; however, none of these 13 employees were included in the CY 2014 institutional disclosure to UT System.

The annual disclosure process is based on what faculty and staff members disclose, and management is relying on them for the accuracy and completeness of disclosures made. The COI office reviews disclosures to determine if it overlaps with a researcher’s research; however, there is no process in place to validate the accuracy and completeness of disclosures made. Incomplete or inaccurate disclosures increases the risk that faculty or staff may be engaged in outside activities that could appear to conflict with their official duties.

The observation described above is considered a high-level finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:** To ensure that disclosures received are reasonably accurate and complete, management should:

- Develop a risk-based process to validate the disclosures received.
- Develop a process, to occur after the annual disclosure process and after the CMS website is updated for an applicable calendar year, to compare amounts reported by CMS to amounts self-reported by faculty, to validate whether disclosures are complete and amounts disclosed are reasonably accurate and include all third parties that have made payments to faculty.
- Using iDisclose, establish a process to identify activities for which prior approval was obtained but for which the activity was not disclosed.
- Update the COIC on results of monitoring activities described above so that the COIC can facilitate corrective action if needed.
- Ensure that all information required to be reported to UT System Administration includes all required information.

**Management’s Response:**

1. Relying on CMS data to verify the accuracy of individual disclosures is problematic given there are no checks and balances with what industry reports to CMS. According to the AMA (July 2016), “…the CMS’ Open Payments program has to date been plagued by significant shortcomings that call into question the accuracy of information published…”

2. In addition, there are feasibility issues in using the CMS data because the site cannot be queried for UTHSCSA employees. To search for UTHSCSA employees, we must perform a separate search of the database using each employee’s name.

3. In the future, we will query the CMS data for specific high risk employees to compare the entities disclosed in both systems. Inconsistencies will be reconciled with the employee and reported to the COIC.

**Anticipated Implementation Date:**

1. Implementation of a risk-based process for comparing CMS records with iDisclose reports, reconciling differences and reporting to COIC will be completed not later than March 31, 2017.

**Timeliness of Disclosures Made**

HOP 10.1.6 states “A covered individual shall submit or update a financial interest disclosure statement using the iDisclose application managed by the Office of the VPR: (1) not later than the 30th day of initial employment,
covering the twelve months preceding the date of disclosure; (2) annually not later than March 31; and not later than the 30th day after acquiring a new financial interest that requires disclosure.” As previously mentioned, all faculty members tested disclosed. However, because of the way the annual disclosures are set up, we could not determine whether all disclosures tested were made within 30 days of discovering or acquiring a new significant financial interest. All disclosures that we reviewed had a start date of January 1st and end date of December 31st. Several outside activities for which faculty members are compensated or for which travel and related expenses are paid by a third party have discrete dates that can occur at any time during the year. As previously noted, the prior approval process for outside activities was not consistently being sought by faculty tested. For instances where payments or in-kind amounts, in aggregate, exceeded $5,000, we could not determine whether such amounts were reported timely.

The observation described above is considered a medium-level finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:**

1. As part of the annual disclosure, require that employees clearly indicate the start and end dates of a disclosed activity.
2. Because payments can be aggregated to get to a significant financial interest, require that covered individuals disclose before that threshold is met if they reasonably believe that the total compensated amount, whether cash or in-kind amounts, will exceed $5,000 for a calendar year.
3. Management should develop a process to monitor disclosures for timeliness. This could include comparing completed prior approvals with disclosures made by the affected faculty, with emphasis on those approved activities that result in a significant financial interest. Management could also use iDisclose to identify changes in disclosures from one year to the next. This would provide insight as to both timeliness of disclosure and whether a disclosed outside activity required prior approval.
4. Update the COIC on results of monitoring activities described above.

**Management’s Response:**

1. The 2015 Annual Report functionality in iDisclose predates our implementation of the prior approval process (Spring 2016). Thus, using the system to identify whether disclosures were made in a timely manner was not possible.
2. Users have the ability to include start and end dates for each disclosed activity. iDisclose allows the COI office to compare disclosures from year to year and to determine if an activity requires prior approval.
3. Now that prior approval is documented in iDisclose, we can develop a process to monitor disclosures for timeliness.

**Anticipated Implementation Date:** April 30, 2017

**Prior Approval of Outside Activities**

HOP 10.1.9 Outside Activities, Prior Institutional Approval states that “employees must obtain prior institutional approval before engaging in certain outside activities and obtain re-approval on an annual basis.” As required, prior approval should be sought for outside employment or other compensated activities, service on outside boards (regardless of whether compensation is received) and any uncompensated activity that would reasonably appear to create a conflict of interest or commitment. According to HOP 1.6.11, Conflict of Interest Committee: Charge, the COIC is required to “advise the Health Science Center on institutional and individual conflict of

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interest, consider any Outside Activity Disclosure Reports that indicate a possible conflict...and any other such tasks as assigned by the Vice President for Research”.

As part of our work, we selected a judgmental sample of 30 faculty members with active research to test various attributes, including whether such individuals had disclosed outside activities that required prior institutional approval. We also selected a judgmental sample of seven institutional leaders to determine whether such individuals had disclosed outside activities that required prior institutional approval. We identified 23 individuals engaged in outside activities where there was no evidence of prior approval being obtained. Of these, we determined that seven participated in outside activities that were not disclosed in CY 2015. We also identified one possible exception related to participation by a faculty member on an advisory board of a for-profit entity. This outside activity was not disclosed but appears on the company’s website, and it is unclear as to whether the faculty member remains a member of that advisory board.

As of November 2015, employees can seek prior approval to engage in outside activities through iDisclose. Once an employee completes a request, the approval is routed to a departmental official and a UTHSCSCA school official for review. Ultimate institutional approval has been delegated to the Vice President for Business Affairs. If implemented well, the process can be efficient, ensure approval before an activity takes place, and provide a clear documented electronic trail of review and approval. Prior to November 2015, faculty and staff were required to seek prior approval through a paper-based process requiring manual routing of documentation across several desks. Consequently, there could be several manual prior approvals that are not entered into the iDisclose system. Whether automated or manual, prior approval ultimately requires an employee to step forward and seek such approval, and it is critical that employees are aware of this requirement and potential risks to the institution. Approval of outside activities is primarily responsibility of the UTHSCA schools and departments. The departments and their respective schools are also responsible for communicating institutional requirements to their respective faculty and working with faculty if the schools or departments become aware that a faculty member is engaged in an outside activity that requires institutional approval. If faculty engaged in research are unaware of the requirement to seek prior approval before engaging in an outside activity, there is a heightened risk that a faculty member could be engaged in an activity that is in conflict with his or her sponsored research or other institutional activity and that corrective action is not taken in a timely manner.

With the new prior approval process through iDisclose, it appears that prior approvals could be monitored. The iDisclose system could be used to compare information provided in annual disclosures to prior approvals processed through iDisclose. If a disclosed activity does not have a corresponding prior approval, management can know what corrective action to initiate, including, but not limited to whether a management plan might be necessary, whether the outside activity should end, or whether affected faculty may need additional education and training.

The observation described above is considered a high-level finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:**
- Given the observed rate of prior approvals not obtained, it is likely that there are other faculty members that have not obtained prior approvals for outside activities. The COI office and each school could work together to ensure that identified faculty and staff have completed the approval process. To identify such faculty and staff, the COI office and the schools could use the annual disclosure in iDisclose and determine whether prior approvals have been obtained for the outside activities. If it is determined that a prior approval had not been obtained, the schools should work with the affected faculty to ensure that they at least obtain approval for the activity that has occurred or is occurring or take other appropriate action.
For CY 2016 and future periods, the COI office and schools should work together to set up a process to identify activities reported in the annual disclosures that require prior approval but did not have a prior approval in iDisclose. As part of this process, the affected schools should work with the faculty to ensure the appropriate approvals are obtained or take other appropriate action. This process could be set up concurrently with or after the CY 2016 annual disclosure period.

In situations where reports identify instances of non-compliance, the information should be forwarded to the affected deans and communicated to the COIC. Additionally, regular updates should be provided on follow-up progress.

Through executive leadership, an official reminder should be provided to faculty and staff indicating that prior approvals must be obtained before engaging in an outside activity that requires prior institutional approval.

For identified faculty members that fail to seek approval for outside activities that require approval, management should consider establishing an escalation process that includes clear expectations.

Management’s Response:
1. The COI office will identify individuals who report activities in the annual report that should have been received prior approval.
2. The names of the employees who did not obtain prior approval will be provided to the applicable Department Chair for appropriate corrective action(s).
3. The Department Chair will be given a deadline for certifying completion of corrective actions.
4. Status of corrective actions by the Department Chairs will be reported to the COIC until the issue is closed.

Anticipated Implementation Date: May 31, 2017

Scope of Conflict of Interest Committee Activities
In accordance with HOP Policy 1.6.11, the COIC is responsible for implementing and overseeing the conflict of interest program and policies, including HOP policies 10.1.6, Conflict of Interest in Research and Disclosure; 10.1.9, Conflict of Interest, Conflict of Commitment and Outside Activities; and 10.1.12, Institutional Conflict of Interest Policy. The purpose of the COIC is to advise UTHSCSA on institutional and individual COI; consider any outside activity disclosure reports that indicate a possible conflict; develop appropriate institutional and individual management plans; and any other such tasks as assigned by the Vice President for Research.

To determine whether the COIC is addressing its responsibilities outlined in institutional policies, we read the COIC meeting minutes, interviewed members of the COIC, and interviewed the COI manager and the assistant vice president for research operations. The emphasis of the COIC and the COI office is identifying and managing reported and identified COI that could impact externally-funded research. This emphasis is appropriate; however, it does not cover the entire scope of COIC responsibilities, which also include COI that could impact the procurement process and patient care. While this audit focused on COI as it relates to research, there were other activities within the COIC’s oversight responsibilities that are not being actively monitored by the COIC or the COI office. Examples include completeness of the annual disclosure process, prior approval of outside activities, and disclosed COI that do not impact sponsored research. We were informed that management and monitoring of COIs that could impact non-research activities is decentralized among the UTHSCSA schools and departments. However, there is nothing documented in the meeting minutes describing activities that the schools and departments undertake to manage non-research related COI. In addition, the COIC is supported by a very small staff that may not have sufficient resources to include activities that extend beyond the scope of their current responsibilities.
Overall, there is a risk that the COIC does not have sufficient information to provide effective oversight of COI related to non-research activities.

The observation described above is considered a **high-level** finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:** To ensure effective institutional oversight of COI for non-research activities, executive management should develop an appropriate governance and oversight structure. In so doing, executive management could consider the following alternatives:

- Retain the current research focus of the current COIC and consider developing a separate COI committee, with appropriate membership, whose oversight includes non-research related COI that could potentially impact other key institutional activities, including procurement and patient care. The new committee would need its own membership and its own administrative support to obtain the information needed for effective institutional oversight. If this option is selected, the COIC may need to be renamed and COI policies contained within the HOP would need to be updated.

- Retain the oversight responsibility of the current COIC and include COI related to non-research activities. If the current COIC adds this oversight responsibility, then the COI office may need additional resources to effectively monitor and facilitate management of non-research related COI. To minimize the need for additional resources, participation by the schools and departments would be needed. This would require establishing clear lines of communication, coordination, responsibilities, and authority between the schools and departments and the COIC.

**Management’s Response:**

1. **The institutional and research conflict of interest committees were merged in 2014. Our experience is that institutional conflicts, outside of research, are so rare that operating a separate committee was not practicable. Expanding the membership/expertise of the existing COIC (see bullet #3) would be an appropriate solution.**

2. **The COI Manager receives lists from the Office of Institutional Advancement and Office of Technology Commercialization to determine institutional COI. In the past, the COI Manager compared these lists with entities identified on individual disclosures. Only where an outside entity appeared on more than one list (overlap) was the issue forwarded to the COI Committee for review. In the future, we will provide the information to the COIC and allow them to identify any potential institutional COI that requires management.**

3. **We will evaluate our membership and look to add member from other key institutional activities, including procurement and patient care.**

**Anticipated Implementation Date: April 30, 2017**

**Conflict of Interest Committee Meeting Attendance and Email Votes**

The COIC met ten times in CY 2015. For three meetings, a quorum of voting members was not met—May 2015, September 2015, and November 2015. In addition, three members attended less than half of the meetings held and four members did not attend four (or 40%) of the meetings held. When a quorum was not met and action items requiring approval was necessary, the members present would vote and the COI manager would seek email votes from members not present. The minutes minutes for the September 2015 and November 2015 included four management plans that required COIC approval. However, supporting documentation of the emailed votes was not maintained by the COI office. Consequently, we could not validate that a quorum of the COIC approved the four management plans.
The University of Texas System Audit Office
Conflict of Interest Audit at The University of Texas Health Science Center at San Antonio
Fiscal Year 2016

The observation described above is considered a **medium-level** finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:** Management should seek opportunities to improve committee meeting attendance. Given the busy schedules of volunteer members, meetings held via teleconference, video conference, or a web-based meeting should be considered. The COIC should also establish a minimum number of live, in-person meetings. The COIC should not vote on approval of a research or institutional management plans if a quorum is not present. Email votes should not occur as it does not permit deliberation of a quorum of members. If a timely vote is necessary, the COIC could, with the assistance of the COI office, convene a meeting via teleconference, video conference, or a web-based meeting to deliberate and vote on a proposed management plan. Minutes for such a meeting should be documented and retained as evidence of action taken by the COIC.

**Management’s Response:**
1. Unlike other federally mandated committees (e.g., Institutional Review Board), there are no regulations governing the quorum requirements for the COIC meetings. Even committees such as the IRB are allowed to approve a subset of official business by an expedited review process (where one member approves on behalf of the committee). Nevertheless, to increase attendance, we will provide the opportunity to attend the COIC meetings via teleconference.
2. Prior to CY2015, the COIC met only as needed. In 2015, the change to monthly meetings put a strain on our membership that resulted in our limited use of email voting out of necessity. We no longer use email voting.

**Anticipated Implementation Date:** Completed.

**Required COI Training**
According to HOP 10.1.6, *Conflicts of Interest in Research and Disclosure*, Education, Section (b), each covered individual must complete COI training before engaging in research at UTHSCSA and at least once every four years thereafter. Additionally, a covered individual who is new to the institution must complete the training before engaging in research. If the covered individual came from another UT System institution, the covered individual could provide evidence of having completed the training at the previous UT institution, provided that the training was taken within the last four years. Finally, a covered individual must complete the training immediately if the individual is found not to be in compliance with policy or the individual’s management plan, or if this policy is revised in a manner that affects the individual’s duties. UTHSCSA uses a system referred to as Knowledge Center to ensure that employees have completed required compliance training on variety of subject matter.

As part of our work, we selected a judgmental sample of 30 faculty members with active research to test various attributes, including whether such individuals had completed required COI training. According to the Knowledge Center records, 29 (97%) completed the training. We also requested and were provided a listing of all new employees hired by UTHSCSA between September 1, 2014 and December 31, 2015. This population of individuals included faculty and staff. From this list, we selected a judgmental sample of 30 employees, focusing on employees with sponsored research to determine whether the selected employees had received COI training. From the procedures we performed, we determined that:
- Only five of the 30 employees (17%) had completed required COI training.
- Of the 25 employees who did not complete or receive training, eight had active NIH awards.
- For six of the eight employees, the NIH grants transferred with the employees from their previous institutions.
• For one employee, the NIH grant was not research related.
• For the remaining employee, the NIH award was applied for through UTHSCSA. Whether this employee had completed required COI training four years ago or less at the previous institution is unknown since management did not confirm this. In addition, management did not have a procedure in place to monitor whether covered individuals had completed required training. Consequently, it appears that this particular employee may not have completed required COI training before completing an application to the NIH or engaging in research for that award.

We were informed that the Knowledge Center system had automatically notified new employees of compliance training requirements. According to the COI office, these notifications had been turned off. Why or when this functionality was disabled is unknown. In addition, there is not a process in place to ensure covered individuals who are new to UTHSCSA have completed COI training in advance of conducting research or to demonstrate, if applicable, that the requirement was fulfilled at another UT institution. Overall, sufficient controls were not in place to ensure all covered individuals have completed requisite COI training. This increases the risk of non-compliance with NIH requirements Final Rule, which states that researchers are expected to complete required training prior to engaging in NIH-supported research or by the issue date of the notice of award issued subsequent to the institution’s anticipated implementation date.

The observation described above is considered a high-level finding in accordance with UT System’s Internal Audit finding classification system.

**Recommendation:** To ensure covered individuals receive required COI training, management should:
- Ensure that the individuals identified from the audit complete the required COI training. Review internal records to determine whether there are any other covered individuals that require COI training and ensure that those covered individuals receive training.
- Develop and implement a process to ensure that covered individuals are completing COI training required by institutional policy.
- Ensure that the Knowledge Center’s automatic notification functionality is restored and working as intended.
- Establish a process to monitor completion of training of required of individuals.
- Implement a process to validate whether a new employee that is transferring an award from a UT institution has completed COI training. Short of that, all new employees should complete COI training concurrent with or soon after arrival on campus.
- Report results of training monitoring activities to the COIC as the COIC could help ensure that timely corrective action is taken, if needed.

**Management’s Response:**
1. The Knowledge Center (KC) functionality has been corrected.
2. All new employees must complete COI training in KC. The error in our process to add new employees has been corrected.
3. Since the audit, over 6,100 employees have completed initial or continuing COI education.
4. Reports of COIC training monitoring activities will be provided to the COIC and elevated as needed.

**Anticipated Implementation Date:** December 31, 2016

**Monitoring of Management Plans**
We requested and were provided institutional and research management plans that were developed and executed during the scope of the audit. All institutional plans and research management plans provided were signed and
agreed to by the researchers and the plans included evidence of multiple levels of review and approval by the COIC, the COIC chair, the Vice President of Research, and the Dean of the School of Medicine. Meeting minutes indicate that management plans were reviewed and discussed as well as updates made to the plans as the COIC deems necessary. Most of these management plans addressed intellectual property in which the UT System Board of Regents has an equity interest. These particular plans were reviewed and approved by the UT System Office of General Counsel and approved by the Executive Vice Chancellor of Health Affairs or his designee.

We also evaluated whether faculty on management plans, completed their annual disclosures. In addition to institutional policy requirements, each research management plan requires that the faculty member on the plan to complete an annual disclosure in iDisclose. Most faculty members reviewed and completed their annual disclosures; however, we identified two faculty members that did not complete their respective disclosures before the end of the reporting period.

We also tested a sample of management plans that were executed in CY 2015 and whose anniversary date occurred on or before March 31, 2016. We tested certain attributes from the research management plans to determine whether the applicable faculty had completed certain agreed upon actions. One management plan tested anticipated participation in a clinical trial involving human subjects. The clinical trial began during the scope of the audit. The research management plan required that the managed conflict be disclosed within the informed consent agreements. We obtained a copy of an informed consent agreement and validated that the managed conflict was disclosed.

We requested and were provided updates for the management plans tested as described above. Tested faculty members were asked to complete a web-based COI questionnaire from the REDCap system. Faculty feedback was used to determine if any changes needed to be made to the management plans and whether any actions need to be taken to address any new conflicts of interest. Currently, information is not reported to the COIC unless there is a change in scope to the management plan.

During the audit, we were informed that the vice president for research has established a standard process for conducting compliance reviews of active management plans. This process was in process of being implemented while the audit was being conducted. In general, there are three triggers that will initiate a compliance review of active management plans:

1. For-cause reviews conducted at the request of the COIC or an official of the institution or as a follow-up to a previous review where critical and/or major issues were identified;
2. Proactive random review; and
3. Voluntary review at the request of the conflicted faculty member

The observation described above is considered a medium-level finding in accordance with UT System’s Internal Audit finding classification system.

Recommendation: The COI office has begun a process to monitor COI being managed. To strengthen this monitoring process, we recommend that the COI office:

- Ensure that all faculty members with active management plans complete their annual disclosures and review these disclosures and validate their accuracy.
- Periodically update the COIC on its monitoring activities of COI management plans, including whether faculty members have met key provisions in their respective management plans. Updates to the COIC can occur at pre-determined points during the year or after the anniversary date of active management plans.
- Update the COIC on conflicts disclosed to Public Health Service (PHS) agencies that require annual disclosures of conflicts that can affect the design or conduct of PHS funded research.
Management's Response:
1. The COI Manager will monitor all active management plans on an annual basis. Monitoring will include ensuring that all faculty with plans complete their annual disclosure and validate their accuracy.
2. The COI Manager will monitor conflicts disclosed to PHS agencies and report these issues to the COIC.
3. The COI Manager will report the findings of monitoring activities to the COIC.

Anticipated Implementation Date: March 2017