

16-303 Review of Research Conflicts of Interest Process

EXECUTIVE SUMMARY

The Office of Research Administration (ORA) is responsible for reviewing all financial disclosures pertaining to research activities to determine whether a conflict of interest exists. ORA's activities are performed in consultation with the Conflict of Interest Committee (COIC), which reviews certain potential conflicts of interest and recommends actions to be taken.

Institutional policy requires covered employees to disclose all outside employment and other financial relationships to the COIC, which reports to the Provost. ORA also oversees the annual certification process which requires all covered employees to confirm either the accuracy of previously disclosed outside relationships or the nonexistence of such relationships. Covered employees include investigators, faculty members, trainees with an appointment of six continuous months or longer, faculty supervisors, and institutional decision makers.

A **conflict of interest** exists when a significant financial interest or outside relationship that could directly influence an employee's performance of institutional responsibilities, including patient care or the design, conduct, and reporting of research.

Source: *Institutional Policy ACA0001*

Audit Results:

Generally, we found that controls and processes are in place for ensuring that covered employees complete annual certifications and submit disclosures. In addition, we determined that:

- Comprehensive policies and procedures are in place for covered employees.
- The COIC plays an active role in governing the conflicts of interest process.
- Management plans for identified conflicts of interest are submitted as needed.

We identified opportunities for improvement related to the following:

- Policies and procedures to govern institutional conflicts of interest
- Controls and processes for public disclosure of financial conflicts of interest
- Timeliness, monitoring, and supporting documentation for disclosures

Further details of our work are outlined in the *Detailed Observations* section below. Other less significant observations have been communicated to management in a separate letter.

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Management's Summary Response:

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before December 1, 2016.

Appendix A outlines the methodology for this project. We appreciate the courtesy and cooperation extended by the personnel in the Office of Research Administration.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA
Vice President & Chief Audit Officer
August 31, 2016

DETAILED OBSERVATIONS

Observation 1:**Finalize Institutional Conflicts of Interest Policy****RANKING: *Medium***

During our review, the Institutional Compliance Office and ORA indicated that institutional conflicts of interest were being handled as they were identified, but that no formal process had been implemented. According to management, a draft institutional policy has been presented to the Shared Governance Committee (advisory council to the President), but has not yet been finalized and implemented.

Institutional policy indicates that policies and procedures shall be written, communicated, promoted, accessible, and used to assure integrity and consistency in processes. Without formal written policies and procedures, management cannot be assured that processes will be performed consistently and according to their expectations.

Recommendation:

Management should continue its efforts to develop and implement a formal policy and procedures related to institutional conflicts of interest.

Management's Action Plan:

Responsible Executive: Dan Fontaine

Owner: Allyson H. Kinzel

Due Date: December 1, 2016

The Institutional Compliance Office intends to initiate the formal approval process for the Institutional Conflict of Interest policy in early September 2016. The policy should receive final approval within sixty (60) days of initiation, at which point it will become the official policy of the institution.

Observation 2:**Ensure Publicly Disclosed Information is Current****RANKING: *Medium***

Federal regulations and institutional policy require that each identified financial conflict of interest be posted on a public website. This information should be updated annually or within 60 days after a new financial conflict of interest is identified.

At the time of our review, the information on the public website had not been updated since 2014. ORA management immediately updated the website information when notified of this observation. When required public disclosures are not made, noncompliance with federal regulations could occur, along with related penalties to the Institution.

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Recommendation:

ORA management should develop and implement a process to ensure that publicly disclosed information is current.

Management's Action Plan:

Responsible Executive: Ethan Dmitrovsky, M.D.

Owner: Wesley Harrott

Due Date: November 1, 2016

Actions to address this will be added to the ORA SOP titled, "Full Committee Review Process" as part of the monthly meeting process.

Observation 3:**Track Repeated Untimely Disclosures****RANKING: Medium**

We noted that ORA identifies untimely disclosures, and the COIC communicates the untimely disclosures in a memorandum to the respective employee. However, ORA does not have a process in place to identify employees who repeatedly submit untimely disclosures. Some of these disclosures represent minimal risk to the institution, while others involve more significant financial relationships, and may therefore represent a higher risk. According to institutional policy, covered employees must disclose outside financial relationships within 30 days of acquiring them, with some relationships requiring prior approval.

When trending information about untimely disclosures is not collected, it cannot be communicated to the COIC or the Provost for consideration of further corrective actions.

Recommendation:

ORA management should establish a process to track and report repetitive noncompliance to the COIC and the Provost using a risk-based approach.

Management's Action Plan:

Responsible Executive: Ethan Dmitrovsky, M.D.

Owner: Wesley Harrott

Due Date: November 1, 2016

ORA will address this by including a reporting process for high risk repeat offenders in the SOP titled, "COI Process for Annual Certification" as part of that annual reporting process.

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Observation 4:**Enhance Monitoring Process****RANKING: Medium**

Current practice is for covered employees to disclose all outside relationships in the institution's conflict of interest database. According to ORA, the reporting of disclosures is monitored on a sample basis by reviewing employee information for selected departments.

While the process appears to be thorough based on our reviews, it could be further strengthened by formalizing the procedures used and by expanding the selection process using risk-based or various sampling techniques. For example, we selected a random sample of individuals and found certain outside relationships that had not been disclosed.

Formal, documented procedures could decrease the risk of inconsistent monitoring across the selected departments. In addition, enhanced sampling techniques, such as random sampling, could increase the potential for identifying undisclosed relationships.

Recommendation:

ORA management should strengthen its efforts for monitoring disclosures by formalizing the procedures used and enhancing the selection process.

Management's Action Plan:

Responsible Executive: Ethan Dmitrovsky, M.D.

Owner: Wesley Harrott

Due Date: November 1, 2016

Procedures will be added to the ORA SOP titled, "Disclosure Compliance Checks and Undisclosed Financial Relationship Assistance Plan" to include a process for random sampling of covered individuals in all departments.

Observation 5:**Ensure Disclosures Have Supporting Documentation****RANKING: Low**

Institutional Policy requires that disclosures of outside financial interests be submitted within 30 days after they occur. We tested 25 disclosures and found that four (16%) did not include any supporting documentation related to their financial disclosures.

- In one instance, the disclosure involved a visiting scientist. The financial disclosure related to employment with a biotechnology company with a current research agreement with MD Anderson.
- Three instances involved outside conflicts of covered family members. Discussions with ORA indicated that they typically do not require supporting documentation of family members' reported disclosures.

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Without proper supporting documentation, there may be limited assurance that disclosures are timely and that all conflicts will be identified and managed appropriately.

Recommendation:

ORA Management should strengthen processes to ensure supporting documentation is maintained for financial interest disclosures, as appropriate.

Management's Action Plan:

Responsible Executive: Ethan Dmitrovsky, M.D.

Owner: Wesley Harrott

Due Date: November 1, 2016

ORA will modify its current SOP titled, "Disclosure-review updated - January 2016" to strengthen our current review processes related to atypical documentation.

Appendix A**Objective, Scope and Methodology:**

The objective of this review was to assess the effectiveness of controls for ensuring the identification, communication, and management of individual and institutional conflicts of interest. The review covered the period of September 2014 through May 2016.

Our methodology included the following procedures:

- Interviewed key personnel and reviewed relevant documentation to understand annual certification and disclosure processes within the Institution
- Reviewed relevant Federal and State regulations, as well as institutional and UT System policies and procedures.
- Reviewed relevant information from the Conflict of Interest database.
- Reviewed training materials and results for a sample of covered employees.
- Assessed compliance with policies and procedures related to submission and review of disclosures, management plans, presidential waivers, and other key processes.
- Interviewed Conflict of Interest Committee (COIC) members to gain an understanding of their roles and responsibilities.
- Reviewed COIC meeting agendas and minutes from September 2014 through May 2016.
- Based on guidance from UT System, determined compliance with 42 CFR 50, Subpart F, Promoting Objectivity in Research.
- Reviewed results of ORA's monitoring process for undisclosed outside relationships.

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing* and *Government Auditing Standards*.

Number of Priority Findings to be monitored by UT System: None

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.*”