



Financial Conflict of Interest

Internal Audit Report No. I2014-108

June 26, 2014

Prepared By

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Reviewed and Approved By

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INTERNAL AUDIT SERVICES
IRVINE, CALIFORNIA 92697-3625

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BRUCE MORGAN
ASSISTANT VICE CHANCELOR FOR RESEARCH
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RE: Financial Conflict of Interest Audit in Research
Report No. I2014-108

Internal Audit Services has completed the review of financial conflict of interest in research and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Mike Bathke

Mike Bathke
Director
UC Irvine Internal Audit Services

Attachment

C: Audit Committee
James Hicks, Associate Vice Chancellor for Research
Grace Park, Principal Subcontract and Research Compliance Officer
Nadia Wong, Conflict of Interest Administrator

I. MANAGEMENT SUMMARY

In accordance with the fiscal year (FY) 2013-2014 audit plan, Internal Audit Services (IAS) conducted a review of financial conflict of interest (COI) in research within the Office of Research. The purpose of the review was to assess the adequacy of the COI management program as a whole and to assess the campus' compliance with the Public Health Service (PHS) revised standards and thresholds for financial disclosure required by institutions that apply for or receive research support from PHS agencies.

Based on the procedures performed, it is our conclusion that overall, the campus COI management program is in compliance with University guidelines, State of California requirements, National Science Foundation (NSF) requirements and the revised PHS standards and thresholds for financial disclosure required by institutions.

II. BACKGROUND

University COI requirements are relatively complex and federal agency regulations in this area are changing and becoming more stringent. The appearance of a COI can undermine public trust, even in situations where mitigating factors are made known to the public.

Research COI Requirements

Applicable state and federal COI regulations have established different requirements for disclosure and review, and financial reporting thresholds for research COI disclosures. The California Fair Political Practices Commission requires that UC campuses use Form 700U to obtain disclosure information from Principal Investigators (PI). A separate Federal disclosure form (NSF Disclosure Form 900 and PHS Form 800) must be completed by the PI and any other individual responsible for the design, conduct or reporting of the results of work performed or to be performed under a NSF or PHS sponsored project. If a positive disclosure is made on any of these forms, additional evaluation is completed. At a minimum, a disclosure is typically required at the time the initial grant proposal is submitted to the sponsor. For NSF and PHS sponsored projects, additional disclosures may be required.

Major changes to the PHS regulations impacting disclosures of research conflicts

Revised financial COI rules were issued by PHS on August 25, 2011 (supplementing those issued in 1995) and took effect on August 24, 2012. The revisions include the following:

- PHS-funded investigators must disclose to their institutions all significant financial interests (SFIs) related to their institutional responsibilities;
- PHS-funded investigators must disclose any equity interests in a non-publicly held company and any sponsored or reimbursed travel (zero thresholds);
- In general, the monetary threshold for reporting SFIs was lowered from \$10,000 to \$5,000;
- Institutions must provide the PHS Awarding component (e.g. NIH) significant additional information on identified financial COI and how they are being managed;
- Only income or travel from seminars, lectures, or teaching engagements sponsored by a federal, state, or local governmental agency, a United States institution of higher education, or a research institute, academic medical center, or hospital affiliated with an institution of higher education is excluded from these regulations (less exclusions);
- Every PHS-funded institution must post on a publicly accessible website, or make publicly available, information on certain SFIs that the institution has determined are related to PHS-funded research and constitute a financial COI;
- All investigators must complete COI training prior to engaging in PHS funded research and at least every four years.

III. PURPOSE, SCOPE AND OBJECTIVES

The purpose of this review was to perform a general review of compliance with applicable state and federal government requirements for disclosing, managing and reporting financial COI.

The review included the following procedures:

1. Reviewed local and system-wide policies related to COI compliance, training and education, and monitoring efforts;
2. Interviewed management and other key personnel responsible for developing and implementing the policies and individuals with process responsibilities;
3. Reviewed and evaluated local practices for compliance with policies and agency regulations;
4. Reviewed practices for reviewing and monitoring reports of disclosures submitted by faculty members including manual and electronic systems/processes;
5. Reviewed practices for evaluating positive disclosures with SFIs and the review process by responsible offices;
6. Reviewed communications and training efforts provided to locations and faculty members;
7. Reviewed processes for discovering undisclosed SFI or COI and mitigating plan to address when discovered; and
8. Reviewed campus COI information systems if any, for data tracking, reporting disclosures, enforcement efforts and associated monitoring for compliance.

IV. CONCLUSION

The campus encourages outside professional activities by faculty that contribute to their respective professions and to the community. COI management has taken a proactive approach with respect to COI awareness, reporting requirements and associated monitoring of compliance, and understands the importance of complying with COI policies and practices to achieve compliance.

Based on our review, the campus COI management program is in compliance with University policy, applicable state and federal regulations, specifically, the revised standards and thresholds for financial disclosure required by institutions that apply or receive research support from PHS agencies. The campus COI compliance program overall, appears to be strong with good COI compliance policies and practices to help identify, disclose and manage various types of conflict of interest, and monitor positive financial COI disclosures. However, the recent changes in PHS regulations and requirements have created a significant increase in workload for researchers, and administrators who manage financial COI's. IAS suggests that an electronic research administration (eRA) management system be considered.

An eRA system will especially be effective in facilitating compliance with current COI regulations, as well as any additional requirements resulting from the new Office of Management and Budget (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (OMB Uniform Guidance). An eRA system will also help to reduce the risk of unintentional non-compliance by creating more efficient and easily understood procedures for COI disclosure reporting.

V. OBSERVATIONS AND RECOMMENDATIONS

1. eRA System Implementation

The recent changes in PHS regulations and requirements have created a significant workload increase for campus researchers, and administrators who disclose and manage financial COI's. Even though the current manual process complies with multiple agencies and regulations, IAS recommends that management consider adopting and implementing an eRA management

system. An eRA system would enable investigators and administrators access to disclosure information, which in turn, would reduce administrative burden by enabling auto-populate functions based on existing data, promote more efficient workflows, allow for better business process controls, result in less errors, accelerate disclosure reviews and approvals and facilitate the expeditious launch of research protocols, grants and contracts.

In addition, federal agency implementation of the OMB Uniform Guidance may result in multiple federal agencies implementing similar, but different, COI policies. If this occurs, it will have a significant impact on the disclosure regulations and requirements, and administrative burden on researchers and staff who already have difficulty meeting the current disclosure requirements.