UCSB Audit and Advisory Services

Internal Audit Report

Research Conflict of Interest

July 13, 2016

Performed by:
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Report No. 08-16-0017

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University of California, Santa Barbara

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July 13, 2016

To: Karen Hanson, Assistant Vice Chancellor for Research
Brandt Burgess, Director of Research Integrity

Re: **Research Conflict of Interest**
Audit No. 08-16-0017

Audit and Advisory Services has completed an audit of Research Conflict of Interest, which was part of the 2015-16 audit services plan. Enclosed is the report detailing the results of our work.

The purpose of this audit was to assess the adequacy of internal controls over campus sponsored research conflict of interest management processes and overall compliance with related University policies and procedures. The scope of the review included the following areas:

- Conflict of Interest Disclosures for Industry Sponsored Research.
- Conflict of Interest Disclosures for Federally Funded Research.
- Monitoring of Positive Conflict of Interest Disclosures.

Based on the results of the work performed within the scope of the audit, there are appropriate processes in place to help ensure compliance with conflict of interest requirements. We did note opportunities to strengthen practices and internal controls over the management of positive conflict of interest disclosures, including developing a formal method for tracking, monitoring, and reporting outstanding items from conflict of interest management condition plans, and developing procedures or guidelines for following up on management condition plan elements.

Detailed observations and management corrective actions are included in the following sections of the report. The management corrective actions provided indicate that each audit observation was given thoughtful consideration, and that positive measures have been taken or are planned to implement the recommendations.

The cooperation and assistance provided by Office of Research personnel during the review was sincerely appreciated. If you have any questions, please contact me.

Respectfully submitted,

Robert Tarsia
Director
Audit and Advisory Services

Enclosure

cc: Chancellor Henry Yang
Vice Chancellor Administrative Services Marc Fisher
Interim Vice Chancellor for Research Joe Incandela
Brian McCurdy, Research Integrity Specialist, FCOI
UCSB Audit Committee
Senior Vice President and Chief Compliance and Audit Officer Sheryl Vacca

UCSB Audit and Advisory Services
Research Conflict of Interest
Audit Report No. 08-16-0017

PURPOSE

The purpose of this audit was to assess the adequacy of internal controls over sponsored research conflict of interest (COI) management processes and overall compliance with related University of California (UC) and University of California, Santa Barbara (UCSB) policies and procedures.

SCOPE, OBJECTIVES, AND METHODOLOGY

The scope of the review included all UCSB sponsored research contracts and grants subject to conflict of interest reporting requirements. Our detailed testing included contracts and grants awarded from July 1, 2015, to May 5, 2016.

The audit objectives were to:

- Determine whether conflict of interest disclosures were submitted in accordance with policy requirements and campus processes for federally funded sponsored research and industry sponsored research.

- Assess if there were any positive disclosures for the audit period and, if so, that there was an approved management plan and compliance monitoring process.

To accomplish our objectives, our detailed work included interviews, direct observations, review of documentation, testing, and other steps, including:

- Research and review of systemwide and campus policies and procedures covering conflict of interest, along with federal and state regulations:

  UC Systemwide Policies

  - *Disclosure of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards,* UC policy dated August 13, 2012.
  - *Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards,* UC policy dated December 23, 2012.
  - Academic Personnel Manual APM 028, *The University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research.*
  - *2014 University of California Conflict of Interest Code,* especially *Title 2, California Code Regulation*, section 18775(d)(1), which identifies when disclosure is not required if the non-governmental entity funding or supporting the research is one of the entities listed in this document.

UCSB

- Research Circular D.5, *Disclosure of Financial Interests Related to Acceptance of Private Funds for Research to Promote Objectivity in Research.*
- Research Circular D.1, *Disclosure of Financial Interests Related to Public Health Service Sponsored Projects for Promoting Objectivity in Research*.
- Research Circular D.3, *Disclosure of Financial Interests Related to National Science Foundation Sponsored Projects for Promoting Objectivity in Research*.
- *Conflict of Interest and Graduate Education,* un-dated policy from the Office of Research website.

Federal

- *National Science Foundation - Investigator Financial Disclosure Policy,* Federal Register, Volume 60 Issue 132, July 11, 1995.
- *Department of Health and Human Services - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors; Final Rule,* Federal Register, Volume 76 Number 165, August 25, 2011.

State of California

- § 18755 Regulations for the Fair Political Practices Commission, Title 2, Division 6, California Code of Regulations*, Statements of Economic Interests: Person or Persons at an Institution of Higher Education with Principal Responsibility for a Research Project.*

- Detailed testing of COI disclosures to determine whether:
  - The selected industry and federally required disclosures were submitted as required by regulations and policies. To perform our testing, we obtained the PI disclosure statements from the ORCOI system and validated the following information: the type of disclosure made (industry or federal) was consistent with the award type; the date the disclosure was submitted; that all of the questions on the form were answered; and that submission reflected information for an electronic signature. In addition, we validated that the disclosure statement was also recorded in the ORBiT system.[1]
  - Disclosures were submitted and reviewed prior to accepting the award funding, when applicable. To perform our testing, we obtained the COI disclosures from the ORCOI system for each of the awards selected for testing. We then validated in the ORBiT system the following information: award title, sponsor name, date the award was approved, and that the COI disclosure date preceded the date that the award funds were accepted.
  - Positive disclosures were reviewed by the Conflict of Interest Committee, as required, and positive disclosures with management conditions were monitored over the duration of the award. To do this testing, we interviewed the Director of Research Integrity and the Conflict of Interest Coordinator to understand the positive disclosure review process. We then obtained and reviewed six months of monthly COI Committee meeting minutes for

[1] ORBiT (Office of Research Bit of Information) is the Office of Research's contract and grant electronic database.

the period November 2015 to April 2016, to ensure that positive disclosures were being reviewed by the COI Committee, that the meeting minutes were signed as required, and to identify any COI Committee required management condition plans with follow-up reporting requirements.

This audit was conducted in conformance with the *International Standards for the Professional Practice of Internal Auditing*.

BACKGROUND[2]

Conflicts of interest or perception of conflicts of interest occur when an investigator's private interests combine with his or her research interests, such that an independent observer may question whether the investigator's research is inappropriately biased by potential financial gain. Conflict of interest refers to a situation in which there could potentially be bias, rather than if an investigator acted inappropriately.

UCSB's research COI requirements are guided by State of California and federal government requirements, which differ in a few key ways. The California Fair Political Practices Commission (FPPC) requires that UC and California State University Principal Investigators (PIs) complete Form 700-U, *Statement of Economic Interest for Principal Investigators* (Form 700-U), for research projects funded, in whole or in part, by a non-governmental entity. This form must be filed each time new funding is received from a nongovernmental entity. The form includes a list of questions used to determine whether the PI has a financial interest in the sponsor of the research, and the PI is required to certify the accuracy of the form under penalty of perjury under the laws of the State of California. Failure to file the required form or properly report a financial interest could subject the PI to civil penalties, such as fines.

For required federal disclosures, UCSB has flexibility in the design of the form, and uses an electronic disclosure system referred to as The Office of Research Conflict of Interest Disclosure System (ORCOI) for disclosures related to projects sponsored by Public Health Service (PHS), National Science Foundation (NSF), and for other agencies adopting the federal requirements. The ~~a~~annual disclosure form at UCSB is titled the *National Science Foundation (NSF) - Annual Disclosure* form. Any investigator who has responsibility for the design, conduct, or reporting of a research project sponsored by an entity adhering to the federal disclosure requirements must disclose any significant financial interests of the investigator and his or her spouse and dependent children that may be related to, or affected by, the research project.

For investigators completing either the Form 700-U or the *National Science Foundation - Annual Disclosure* form, if there is a positive disclosure meeting certain criteria[3], a *Disclosure of Economic Interests: Addendum* must be completed and submitted to the Office of Research. All positive disclosures are reviewed by the Conflict of Interest Coordinator, who may follow up with the investigator and obtain additional information related to the potential conflict of interest. The relevant information is presented to the Conflict of Interest Committee (COI Committee) for the independent review of conflict of interest under research proposals. The COI Committee is composed of seven voting members, six faculty members and the Director of Technology and Industry Alliances, and three non-voting staff from the Office of Research. The COI Committee

[2] Source: Campus Office of Research website, interviews with Office of Research staff, and auditor analysis
[3] 700U- positive disclosures of position, investment, income, loans, or gifts. NSF- positive disclosures meeting sponsor specific thresholds.

reviews the information presented and advises the Vice Chancellor for Research whether the funding for the research project should be accepted based on the potential conflict of interest and, if so, what management conditions, if any, are needed to manage the potential conflict. The Vice Chancellor has final approval and can accept the recommendations of the COI Committee as proposed, or with modifications. Funding for the research project is not released until the Vice Chancellor determines that management conditions are sufficient.

SUMMARY OPINION

Based on the results of our work performed within the scope of the audit, there are appropriate processes in place to help ensure compliance with COI requirements. We did note opportunities to strengthen management practices and internal controls over the management of positive COI disclosures by developing a formal method for tracking, monitoring, and reporting outstanding items from conflict of interest management condition plans, and developing procedures or guidelines for following up on management condition plan elements.

DETAILED OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

A. Compliance with Conflict of Interest Disclosure Requirements

Industry Sponsored Awards - Form 700-U Submission

- We selected a sample of 15 industry-sponsored awards active during fiscal year 2015-16 from the ORBiT *Proposals Awarded by Department/PI* report dated May 5, 2016, and determined whether disclosures were submitted in accordance with policy requirements and established campus processes. We obtained the PI disclosure statements from the ORCOI system and validated the following information: the date the disclosure was submitted, that all of the questions on the form were answered, and that the disclosure submission reflected information for an electronic signature. In addition, we validated that the disclosure statement was also recorded in the ORBiT system. Finally, we verified, using the ORBiT system, that funding was not accepted for the selected award prior to filing of the disclosure. All 15 disclosure submissions audited complied with policy requirements and campus processes.

Federally Sponsored Awards – National Science Foundation (NSF) - Annual Disclosure Form

- We selected a sample of 15 federally sponsored awards active during fiscal year 2015-16 from the *ORBiT Proposals Awarded by Department/PI* report dated May 5, 2016, and reviewed copies of the associated disclosure forms from the ORCOI system to ensure that PI annual COI disclosures had been filed. We validated the following information: the date the disclosure was submitted, that all of the questions on the form were answered, and that the disclosure submission reflected information for an electronic signature. In addition, we validated that the disclosure statement was also recorded in the ORBiT system. Using the award processing information from the ORBiT system, we also validated that funding was not accepted unless there was an annual disclosure on file. In all cases, the disclosure forms were submitted completely and timely, prior to accepting award funding.

B. Positive Disclosures

Positive COI Disclosure with Management Condition Plan

To ensure that positive disclosures were handled in accordance with UCSB policy and procedures, we requested a list of the positive COI disclosures with required management condition plans for awards active during the last two fiscal years. The Office of Research reported that there was only one positive disclosure with a management condition reporting requirement during this period. We reviewed the positive disclosure to determine whether:

- A management plan had been documented.
- The Vice Chancellor for Research signed the COI Committee minutes documenting acceptance of the management plan, as required.
- Funds were not released until the reported conflict of interest was accepted as manageable by the Vice Chancellor for Research.

We found that:

- A management plan had been documented.
- There were meeting minutes, approved by the COI Committee, and the Vice Chancellor for Research signed the minutes indicating acceptance of the committee's recommendations. Since this was an award that was continued annually since 2001, we also validated that the recent management plan condition submission made by the PI addressed all of the management conditions that were documented in 2001, and that the COI Committee meeting minutes acknowledged compliance with the management condition plan requirements.
- The award funding was not released until the Vice Chancellor for Research accepted the management plan.
- There were no adverse findings from this review.

C. Monitoring of Positive Disclosures

Monitoring Practices

To reduce potential bias or the perception of bias in research as well as comply with UC policies and state and federal regulations, positive disclosures of potential conflicts of interest are reviewed by the COI Committee. The COI Committee assesses the details of disclosure and the research project, then advises the Vice Chancellor for Research whether the funding for the research should be accepted and, if so, what conditions are needed to manage the potential conflict. The Vice Chancellor makes the final determination regarding funding acceptance and conflict of interest management strategies. The COI Committee's recommendations are documented in the meeting minutes, which are signed by the Conflict of Interest Coordinator and committee chair. The Vice Chancellor for Research also signs, indicating if the recommendation of the committee is accepted as-is or with specified modifications.

There is no systematic process in place for tracking outstanding items from conflict of interest management condition plans, and also currently no written guidelines for procedures to use for following up on the implementation of management condition plan elements that the COI Committee has required. The current practice is to have the PI accept the management conditions imposed by the committee via email response; however, there is no further feedback to the COI Committee that the management condition plan has been satisfied unless the COI Committee specifically stipulated a reporting requirement. To improve monitoring of positive conflict of interest management condition plans, the Conflict of Interest Coordinator should develop a formal method for tracking, monitoring, and reporting outstanding items from conflict of interest management condition plans. The Conflict of Interest Coordinator should also develop procedures or guidelines for following up on management condition plan elements.

Management Corrective Actions

The Conflict of Interest Coordinator will develop and document in a written procedure a formal method of tracking, monitoring, and reporting management condition plans. The process will include:

- A designated person and a specific follow-up date for each management condition plan.
- Required status reporting, by the responsible PI or assigned individual, to the Conflict of Interest Coordinator and/or or presentation at a COI Committee meeting.
- Guidelines for evaluating the updates received and reporting, with recommendations, to the COI Committee.

Audit and Advisory Services will follow up on the status of this issue by October 1, 2016.