

UCSB AUDIT AND ADVISORY SERVICES

February 10, 2011

To: Executive Vice Chancellor Gene Lucas
Vice Chancellor for Research Michael Witherell

Re: **Conflict of Interest – Conflict of Commitment**
Audit Report No. 08-11-00008

As part of the 2010-11 annual audit plan and in conjunction with a UC system-wide effort, Audit and Advisory Services conducted an audit of UCSB's compliance with selected UC and campus Conflict of Interest (COI), Conflict of Commitment (COC), and faculty and staff income reporting policies, procedures, and guidelines. Enclosed is the audit report detailing the results of our review.

The purpose of the audit was to assess the adequacy of internal controls over campus COI and COC management processes and overall compliance with University policy. Review procedures focused on existing policies and practices and required disclosures for research conflict of interest and faculty conflict of commitment. The scope of the review included discussions with Office of Research and Academic Personnel staff and limited testing in the following areas:

- COI Disclosures for Industry - Sponsored Research
- COI Disclosures for Federally Funded Research
- Monitoring of Positive COI Disclosures
- Prior Approval for Faculty Involvement in Category I Outside Professional Activities
- Annual Report of Category I and II Compensated Outside Professional Activities
- Comparative Testing of COC and COI Disclosure Information

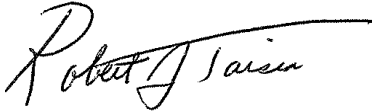
Based on the results of the work performed within the scope of the audit, there are processes in place to help ensure compliance with COI and COC requirements. However, we noted opportunities to improve and strengthen management practices and internal controls in the areas of clarification of policies, prior approvals for COC category I activities, tracking and management of conflicts of interest, and sharing and comparing COI and COC data.

We have included a copy of our detailed observations and management corrective actions with this cover memo. The management corrective actions provided indicate that each audit observation was given thoughtful consideration and that positive measures have been taken or planned to implement the management corrective actions.

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Vice Chancellor for Research Michael Witherell
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The cooperation and assistance provided by Office of Research and Academic Personnel staff during the review was sincerely appreciated. If you have any questions, please feel free to contact me.

A handwritten signature in black ink that reads "Robert Tarsia". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Robert Tarsia
Acting Director
Audit and Advisory Services

Enclosure

cc: Chancellor Henry Yang
Associate Vice Chancellor Ron Cortez
UCSB Audit Committee
Senior Vice President and Chief Compliance and Audit Officer Sheryl Vacca
Associate Vice Chancellor Jack Talbott
Assistant Vice Chancellor Karen Hanson
Director Bruce Hanley
Director Cindy Doherty

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Performed by:

Daniel Samec, Staff Auditor

Approved by:

Robert Tarsia, Acting Director

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Audit Report No. 08-11-00008

Purpose and Scope

The purpose of the audit was to assess the adequacy of internal controls over campus Conflict of Interest (COI) and Conflict of Commitment (COC) management processes and overall compliance with University of California (UC) policy. Review procedures focused on existing policies and practices and required disclosures for research-related COI and faculty COC. The scope of the review included discussions with Office of Research and Academic Personnel staff and limited testing in the following areas:

- COI Disclosures for Industry - Sponsored Research
- COI Disclosures for Federally Funded Research
- Monitoring of Positive COI Disclosures
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- Comparative Testing of COC and COI Disclosure Information

Background

Conflict of Interest in Research

According to the UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects, 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. Such situations are becoming more common at universities as investigators are more frequently interacting with industry. The National Institutes of Health (NIH) is one federal agency that is proposing to impose stricter requirements related to conflict of interest.

University of California, Santa Barbara's (UCSB) 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

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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. 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 has created the Form 800-U Disclosure of Financial Interests Related to Projects Sponsored by PHS, NSF or other Agencies Adopting the Federal Requirements (Form 800-U). 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 Form 800-U, a Disclosure of Economic Interests: Addendum must be completed and submitted to the Office of Research if there is a positive disclosure. 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 Committee for the Independent Review of Conflict of Interest Under Research Proposals (COI Committee), which is composed of seven faculty members and three non-voting staff from the Office of Research. The COI Committee 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.

Conflict of Commitment

The services of UCSB faculty members are often in high demand from outside entities due to their specialized knowledge and skill set. As noted in the UC Academic Personnel Manual, Section 25, (APM 025), the University acknowledges that faculty members' involvement in activities with entities outside the University can help advance and communicate the specialized knowledge of the faculty

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members, and is supportive of the University's goal of increasing and sharing knowledge. It is important, however, that the outside activities of faculty members do not interfere with their University obligations, including classroom teaching, conferring with students, research, committee work, administration, and public service. Otherwise, the activities result in a conflict of commitment.

APM 025 provides guidance on addressing potential conflicts of commitment, whether compensated or uncompensated, and involving students in outside professional activities of faculty. APM 025 identifies three categories of outside professional activities:

- Category I - Activities that are likely to raise issues of conflict of commitment.
- Category II - Activities that are unlikely to raise issues of conflict of commitment and are ordinarily accepted as regularly performed, compensated outside professional activities.
- Category III - Activities that are integral to all disciplines and ordinarily do not present issues of conflict of commitment.

Faculty members are required to obtain prior approval for category I activities and report annually on category I and II activities. APM 025 also imposes annual time limits on faculty members' outside professional activities. UCSB's local guidance for faculty involvement in outside professional activities is the "Red Binder": UCSB Campus Policies and Procedures for Academic Personnel, Section I-29, Conflict of Commitment and Outside Professional Activities.

Summary Opinion

Based on the results of the work performed within the scope of the audit, there are processes in place to help ensure compliance with COI and COC requirements. However, we noted opportunities to improve and strengthen management practices and internal controls in the areas of clarification of policies, prior approvals for COC category I activities, tracking and management of conflicts of interest, and sharing and comparing COI and COC data.

The audit observations and management corrective actions are detailed in the remainder of the audit report.

Detailed Observations and Management Corrective Actions

A. Compliance with Conflict of Interest Requirements

1. Industry-Sponsored Awards

UCSB had approximately 160 active awards from industry sponsors during fiscal 2009-10. The California FPPC requires UC and California State University PIs to complete Form 700-U for research projects funded, in whole or in part, by a non-governmental entity. The form includes a series of questions used to determine whether the PI has a financial interest in the sponsor of the research; 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.

a. Policies – Research Circular D.5

UCSB Sponsored Projects Policy Research Circular D.5, Policy on Acceptance of Private Funds for Research, currently states that, in addition to required upfront disclosures, Form 700-U disclosures are required “within ninety days after expiration in the case of a contract or grant, or after funds have been completely expended in the case of a gift.” The Research Conflict of Interest Coordinator indicated that this was an outdated requirement and not a current business practice. To properly align the policy with current business practices, Research Circular D.5 should be updated.

Management Corrective Action

The Office of Research acknowledges that this is an outdated requirement, and is not current practice. Research Circular D. 5 will be amended during the first quarter of 2011 to eliminate this requirement. An amended policy will be provided to the campus Policy Coordinator.

b. Form 700-U Submission

To determine whether UCSB is complying with state law as well as UC and UCSB policy related to conflict of interest for industry-sponsored research, Audit and Advisory Services selected a judgmental sample of 22 industry-sponsored awards active during fiscal 2009-10 and determined whether disclosures were submitted in accordance with policy requirements

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and established campus processes. In all cases, the appropriate forms were submitted. In one case, however, a department chair signed on behalf of the PI. The PI was unavailable for signature, and the department staff confirmed with the PI that he had no reportable financial interest related to the sponsor. The Form 700-U, however, is certified by the signatory under penalty of perjury, and the investigator is both the required signatory and the individual most knowledgeable of his or her financial interests. The Office of Research may want to remind appropriate personnel of this requirement and communicate expectations for disclosures in cases when the PI is unavailable.

Management Corrective Action

The Office of Research acknowledges that, in one known case, a department chair signed a COI disclosure for a faculty member in their absence. The Office of Research now examines each disclosure for appropriate signatures by the disclosing party.

Audit and Advisory Services will follow up and verify completion of the corrective action by April 15, 2011.

2. Federally Sponsored Awards

a. Form 800-U

Form 800-U has conflicting language regarding disclosure requirements. In one instance, the form indicates that the lead PI is certifying that the form provides “a complete disclosure of... significant financial interests related to the project.” In another place, the form asks whether the researcher, spouse, or dependent children “have any significant financial interest and/or related financial interests to the work being conducted.” From the way the form is written, it is unclear whether disclosure is required for financial interests that are significant *and* related, or significant *or* related. The Conflict of Interest Coordinator indicated that researchers are only required to disclose financial interests that fit both the definition of significant and the definition of related. To eliminate potential confusion, the wording of Form 800-U should be revised.

Management Corrective Action

The Form 800-U has been modified to read “and/or” in both cases. The old form has been replaced on the Office of Research website.

b. Form 800-U Submission

A investigator who has responsibility for the design, conduct, or reporting of a project sponsored by the National Science Foundation, Public Health Service (including NIH), and certain other agencies must disclose all significant financial interests of the investigator and his or her spouse and dependent children related to, or affected by, the sponsored project. To ensure compliance with federal regulations, Audit and Advisory Services selected a judgmental sample of 48 federally sponsored research awards active during FY 2009-10 and obtained copies of the associated disclosure forms. In all cases, the required disclosures had been completed.

3. Monitoring of Positive Disclosures

To reduce potential bias or the perception of bias in research as well as comply with UC policy 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. The Committee 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 COI 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.

a. Monitoring Practices

The Conflict of Interest Coordinator indicated that there is no systematic process in place for tracking outstanding items from conflict of interest management plans, and no written guidelines for procedures to use for following up on the implementation of management plan elements, such as using public databases of business ownership to monitor positive conflicts of interest. To improve monitoring of positive conflicts of interest, the Conflict of Interest

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Coordinator could develop a formal method of tracking outstanding items from conflict of interest management plans that are subject to verification, along with written guidelines for steps to take to follow up on the implementation of certain management plan elements.

Management Corrective Action

The Office of Research strongly feels that it is the responsibility of faculty members to disclose their financial interests, and to maintain compliance with any required conflict management practices. The Office of Research also understands that limited compliance monitoring may be in the best interests of the campus. The Office of Research has begun (as of 1/1/2011) to follow up on certain managed conflicts which are complex, or may depend on changing faculty positions or ownership in outside entities. These are being tracked annually, since some conflict management reports are required on an annual basis.

Audit and Advisory Services will follow up and verify completion of the corrective action by April 15, 2011.

b. Positive Disclosures

To ensure that positive conflict of interest disclosures were handled in accordance with UCSB policy and procedures, Audit and Advisory Services selected a judgmental sample of 10 positive disclosures for awards active during fiscal 2009-10 and determined whether:

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

The following was noted:

- For all 10 positive disclosures, there were meeting minutes, approved by the Conflict of Interest Committee Chair, documenting a management plan, and in all 10 cases the Vice

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Chancellor for Research signed the minutes, indicating acceptance of the Committee's recommendations.

- In all cases, the funding was not released until the Vice Chancellor for Research accepted the management plan.
- The ten management plans were documented in eight sets of meeting minutes. Of the eight Committee meeting minutes reviewed, however, only two sets were prepared and signed within a timely manner. The other six were prepared and signed over six months after the Committee meeting.

To ensure that COI management plans and their approvals are timely documented, an internal policy could be developed documenting a reasonable timeframe for finalizing and approving COI Committee minutes.

Management Corrective Action

As of 11/1/2010, all COI meeting minutes are prepared and signed prior to the following meeting.

Audit and Advisory Services will follow up and verify completion of the corrective action by April 15, 2011.

B. Compliance with Conflict of Commitment Requirements

1. APM 025 Reporting Population

Academic Personnel developed an electronic process for submission, tracking, and reporting on the required APM 025 annual reports. The Director of Academic Personnel indicated that the electronic system tracks only Academic Senate ladder faculty members, which does not include individuals with visiting or adjunct professor titles due to the temporary nature of their positions. However, visiting and adjunct professor titles are required to submit the annual reports according to APM 025. Academic Personnel should obtain guidance from University of California Office of the President (UCOP) on whether faculty with these titles should be subject to annual reporting requirements, and either require annual reporting or provide feedback to UCOP on how to align the policy with practice.

Management Corrective Action

Academic Personnel will provide feedback to the Office of the President regarding the reasons for not including temporary appointments in the reporting and suggest alignment of policy with current practice. Our understanding is that most, if not all, other campuses also do not do collect reports for temporary appointees. Action to be taken by June 30, 2011.

2. Annual Disclosure

a. Submission

The electronic reporting process made it possible for Audit and Advisory Services to determine which faculty members had submitted their reports before the November 1, 2010, deadline required by APM 025. The audit found that approximately 63% of the faculty had submitted their reports before the deadline; excluding faculty members who had separated from the University during fiscal 2009-10, approximately 66% of the faculty had submitted their reports on time. Discussion with the Director of Academic Personnel indicated that faculty members receive an annual reminder to complete the APM 025 report, and that this was the first year that Academic Personnel would follow up with department chairs. Academic Personnel should continue to develop and refine the follow-up and escalation process for timely submission of required annual reports.

Management Corrective Action

Academic Personnel has generated lists of outstanding reports and intends to do follow up with department chairs in order to increase the submission rate in a more timely manner. Action to be taken by Feb. 28, 2011.

b. Approval Date

The APM 025 annual reports for fiscal 2009-10, which were due before November 1, 2010, require review and approval by the relevant chair(s) or dean. The audit found that only 37% of the required approvals were obtained before November 1, 2010. Audit and Advisory Services noted that no time frame for review and approval has been established at the UC or UCSB level. Since the reports are required to be submitted before November 1st, Academic Personnel

could provide input to UCOP for establishing a reasonable timeframe for the chairs and deans to review and approve the reports.

Management Corrective Action

Academic Personnel will seek guidance from Office of the President concerning establishment of an “approved by” date. Action to be taken by June 30, 2011.

c. Review of APM 025 Reports

Audit and Advisory Services selected a judgmental sample of 25 faculty members’ annual reports and reviewed the reports to determine whether the report included all the information required by APM 025, activities were properly categorized, and the number of days reported for category I and category II activities did not exceed the applicable limit specified by APM 025. The audit found that:

- For all 25 reports, the number of days reported did not exceed the applicable limit specified by APM 025.
- In two cases, faculty members did not complete all fields, although the electronic form developed by Academic Personnel contains all the fields required by APM 025.
- In five cases, it could not be determined whether the faculty members properly categorized their activities based on the policy and the amount of information provided.

The following are examples of the five cases of reported activities requiring clarification to ensure that there is proper reporting and compliance:

- Two faculty members were listed as chief technology officers of start-up companies. Both faculty members described the nature of the relationship as consulting, but one faculty member indicated the activity was a category I activity, while the other faculty member indicated the activity was a category II activity. Establishing a relationship as a salaried employee outside the University is considered a category I activity, but start-up companies may or may not compensate employees with a salary. Discussions with the Director of Academic Personnel indicated that the position of chief technology officer for a start-up company could be an executive/managerial position, which is considered category I, or

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could be a consulting position, which is considered category II, depending on the nature of the work performed.

- In another case, a faculty member reported serving as a consultant to a federal commission. Consulting is considered a category II activity, but serving on a federal, state, or local government agency committee, panel, or commission is considered a category III activity, which does not need to be reported. Discussion with the Director of Academic Personnel indicated that faculty members are advised to report the activity when they are unsure if an activity is category II or category III.

Academic Personnel could implement additional measures to ensure that all fields are completed and include all information needed to reasonably determine compliance. The electronic reporting system could be altered to create an error message when faculty members do not complete all required report fields. Academic Personnel should also obtain guidance from UCOP to clarify the reporting categories, and determine if additional information needs to be collected on the reports. In particular, since most faculty members describe the nature of their relationship with outside entities as consulting, the policy could be clarified to include a more specific definition of consulting that could be reiterated in the annual email reminder.

Management Corrective Action

Academic Personnel will request guidance from UCOP to clarify the reporting categories, and determine if additional information needs to be collected on the reports. Academic Personnel will also review the current on-line submission form to see if modification related to completion of all fields would be helpful. Action to be taken by June 30, 2011.

3. Prior Approval for Faculty Member to Engage in Category I Activities

APM 025 states that no category I activity may be undertaken without prior written approval. Section I-29 of UCSB's "Red Binder" requires the department chair to review each request for prior approval and endorse or deny the request. The request is then forwarded to the dean for approval. To test compliance with this policy, Audit and Advisory Services selected all 31 faculty members who had reported category I activities as of November 4, 2010, and determined whether prior approval had been obtained. The results showed that:

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- For 20 faculty members, there was no documentation for prior approval at Academic Personnel, the department, or at the college/school level.
- For six of the eleven faculty members who received approval for category I activities, the approval was not completely prior to the activity.
- For four of those eleven faculty members, there was documentation of the approval of the dean, but no documentation regarding endorsement or denial by the chair.

Audit and Advisory Services also noted that some of the activities reported as category I, such as review of research proposals for a federal agency, did not appear to fit the definition of category I activities.

Based on our review, Audit and Advisory Services recommends the following:

- It appears that faculty members do not fully understand the APM 025 activity categorization and prior approval requirements as currently written. To provide clarification, a Frequently Asked Questions (FAQ) section related to APM 025 could be developed, posted on the Academic Personnel website, and linked in the annual reminder email.
- Academic Personnel may also want to follow up with the faculty who did not obtain prior approval, to gain an understanding of why prior approval was not obtained and if the faculty member will continue the activity in the future.
- The prior approval form could be updated to include space for both the dean's and the chair's signatures.
- Academic Personnel could develop a system for tracking prior approvals and comparing activities reported to prior approvals. An electronic prior approval system could make the prior approval process more efficient. If this issue is prevalent system-wide, a standardized UC electronic prior approval system could be developed.

Management Corrective Action

Academic Personnel will begin work on an on-line submission and approval process for Category I prior approvals. Academic Personnel will also investigate communication and training option to better assure awareness of the need for prior approval on Category I activities. Action to be taken by June 30, 2011.

C. Comparative Testing of Disclosure Information

The audit found that conflict of interest and conflict of commitment data are not compared or shared between the Office of Research and Academic Personnel. Though the type of information requested for COI disclosures and APM 025 annual reporting is not exactly the same, some of the information is similar. To determine whether consistent information is obtained from faculty members, Audit and Advisory Services selected 10 faculty members, and compared their APM 025 Reports and COI disclosures for awards active during fiscal 2009-10. The following was noted:

- In three cases, it was clear that faculty provided consistent information.
- In six cases, it was unclear whether information was consistently provided. The faculty members indicated managerial positions in companies that they did not report on their Form 800-U's for federal disclosure. Disclosure for federal awards is only required, however, if the financial interest is related to work performed on the research award, which Audit and Advisory Services was unable to determine without additional follow up.
- In one case, it was unclear whether all consulting payments were consistently reported, as the faculty member did not list names of the businesses from which consulting payments were received on the APM 025 report. APM 025 does not currently require reporting of the names of the entities for which services were provided; it only indicates that the faculty member will be required to identify the entity verbally if requested by the Chancellor or his designee.

Since information from COI disclosures and APM 025 annual reporting may overlap, the Office of Research and Academic Personnel could share and compare reported data, providing an important check on the accuracy of reported information for both processes. For example, the Conflict of Interest Coordinator could follow up with the faculty members who reported managerial positions in their APM 025 reports but not on the COI disclosures, to ensure that the managerial positions are not related to their research awards. It should also be noted that academic departments may have access to both sets of information in some cases, and could compare the data. It may be advisable to consult with UCOP on any policy revision, and process or system implementation, related to this area.

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Management Corrective Action

UCSB does not currently have the resources to develop a comprehensive joint reporting system or comparative system between the COI disclosures and APM 025 reporting. Office of the President will be provided feedback on the results of the audit and the need for this joint/comparative reporting, and it will be suggested that a system-wide solution would be preferable to an individual campus solution. Action to be taken during the first quarter of 2011.