

University of California
San Francisco



Audit Services

December 17, 2010

EMILY STRATTON
Manager
Conflict of Interest

**SUBJECT: Conflict of Interest/Conflict of Commitment
Audit Services Project #11-027**

As a planned system-wide review for fiscal year 2010-2011, Audit Services has completed a review Conflict of Interest/Conflict of Commitment. Attached is the final report incorporating the results and the agreed upon management corrective actions.

The management actions specified in this report will be added to the Audit Services follow-up system. Periodically, you will be contacted to ascertain the status of implementation. Once implemented, additional audit procedures may be performed to validate actions taken. You will be notified when all corrective actions have been implemented and we consider this audit closed.

I would like to thank you for your assistance and cooperation during this review. Please do not hesitate to contact me at 502-2238 should you have questions.

Sincerely,

A handwritten signature in blue ink that reads 'Rick Catalano'.

Rick Catalano
Director

c: Associate Vice Chancellor Boyd
Professor Lang
Interim, Associate Vice Chancellor Roberts

Audit Committee Members

Chief Medical Officer Adler
Executive Vice Chancellor Bluestone
Vice Chancellor Harel
Vice Dean Hindery
Chief Operations Officer Jones
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Associate Dean Schultz
Chief Financial Officer Strickland
Senior Vice President Vacca
Associate Vice Chancellor Vermillion

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT SERVICES**

**Conflict of Interest/Conflict of Commitment
Project #11-027**

December 2010

Fieldwork Performed by:

Julia Mathis, Senior Auditor

Reviewed by:

Tom Poon, Associate Director

Approved by:

Rick Catalano, Director

**Conflict of Interest/Conflict of Commitment
Project #11-027**

MANAGEMENT SUMMARY

As a planned system-wide review for fiscal year 2010-2011, Audit Services performed a review of selected University of California, San Francisco (UCSF) campus Conflict of Interest (COI) and Conflict of Commitment (COC) disclosures. University COI requirements are relatively complex and federal 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.

The purpose of the audit was to assess the adequacy of internal controls in campus research COI and COC management processes, and overall compliance with University policies. The scope of the review excluded UC Conflict of interest policies addressing disclosure requirements for UC designated officials, employee/vendor relationships, hiring of near relatives, patents and technology transfers and use of University resources, Health Sciences Compensation Plan outside income and any COI/COC policies related to the Senior Management Group.

Based on work performed, internal controls surrounding the reporting of Research COI and COC reporting were generally in compliance with existing policies and reporting requirements. Specifically for COC reporting, we found that in general, departments are aware of the existing deadlines for submission of Annual Reports by applicable faculty. While some departments were found to have received the Annual Reports after the November 1, 2010 deadline, the majority of departments are adequately monitoring, tracking, and following up with their staff to ensure that all reports are received in a timely manner. All COC reporting is done on a self-reporting basis and disclosures must be reviewed by the Department Chairs; however review of reports does not have a deadline specified in Academic Personnel Manual (APM) APM-025 and some reports received had not been reviewed at the time of the audit.

Two areas of improvements were noted: 1) the campus has not established an Institutional Conflict of Interest Policy to manage financial conflicts of interest and meet accreditation requirements by the Association for the Accreditation for Human Research Protection Programs, Inc. (AAHRPP); and 2) the UCSF Conflict of Interest Advisory Committee (COIAC) should define which actions recommended to faculty will be followed up to confirm respective faculty have properly addressed reported conflict of interest matters.

More detailed information can be found in the body of this report.

**Conflict of Interest/Conflict of Commitment
Project #11-027**

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I. BACKGROUND

As a planned system-wide review for fiscal year 2010-2011, Audit Services performed a review of University of California, San Francisco (UCSF) Conflict of Interest (COI) and Conflict of Commitment (COC) disclosures. This review focused on policies and conflict of interest disclosures related to research, as well as faculty conflict of commitment disclosures.

University COI requirements are relatively complex and federal regulations in this area are changing and becoming more stringent. The State of California and the Federal government have established different requirements for disclosure and review, and financial reporting thresholds for research COI disclosures. UC campuses use Form 700U (as required by the State of California) to obtain disclosure information from Principal Investigators (PI) and a separate Federal disclosure form 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 the sponsored project.

Responsibilities for the collection, review and approval of conflict of commitment disclosures have been delegated to the Deans and Department Chairs. Compensated outside professional activities are classified in three categories. Category I activities are considered the most likely to cause potential conflicts of commitment and must be pre-approved, while Category II activities are not considered high risk for conflict of commitment and typically do not need any pre-approval; Category III activities are considered integral to all disciplines and are not considered a risk.¹ Faculty members must disclose time spent on compensated Category I and Category II activities annually via the "*Report of Category I and Category II Compensated Outside Professional Activities and Additional Teaching Activities*" (Annual Reports).² The Department Chair is relied upon to recognize a potential conflict, with advice from other University offices as needed.

At UCSF, Research COI is managed centrally by the Conflict of Interest Advisory Committee (COIAC), which collects monitors and makes decisive actions on potential employee conflicts of interest. COIAC requires faculty members to submit financial disclosure forms (1) at the time of proposal submission for research funding, (2) when research gift funding is received, and (3) when an application for protocol is submitted to the CHR for a clinical study.³ The COIAC meets monthly, reviews the applicable forms and discusses potential actions on

¹ APM-025- General University Policy Regarding Academic Appointees.

² Category I activities are the only activities defined in APM-025 as likely to raise a conflict of commitment for faculty; Categories II and II are considered unlikely to do so.

³ Forms collected are 700U and the COIAC Compliance with UCSF Policy #11 form, if applicable; the Principal Investigator Certification Form (and the Disclosure of Financial Interests form, if applicable), and the UCSF CHR Financial Interest Supplement: Disclosure of Investigators' Financial Interests.

each COI with potential conflicts. Each reported conflict will go through either an expedited review, in which the COIAC Manager reviews the information and is authorized by the COIAC to approve the conflict on an expedited basis, or full review which a 10 page questionnaire is sent to the PI, and an informational packet is put together for the COIAC. A summary is compiled with all of the information related to the project and a lead reviewer is assigned (must be a faculty member on the committee). The committee will then votes on the course of action to take.

The COIAC works diligently to review all reported potential conflicts and identifies procedures to mitigate their effects. Several recommendations may be made to the faculty member to ensure that conflicts are appropriately addressed, but follow-up on these items is of critical importance. By nature, COI and COC can be difficult to address as both functions are self-reporting by faculty and full disclosure can't be assured, and the interpretation of requirements may not always be completely clear.

II. PURPOSE AND SCOPE

The purpose of the audit was to assess the adequacy of internal controls in campus COI and COC management processes, and overall compliance with University policies.

To complete the review, the following procedures were performed:

- School personnel responsible for COC and the COIAC Manager were interviewed to determine:
 - How members of the faculty/staff are made aware of the COI/COC policies and their responsibilities. The actions that are taken to evaluate and monitor positive COI/COC disclosures.
 - Existing processes for submitting, evaluating and monitoring COI and COC disclosures and for identifying, disclosing and managing non-financial conflicts of interest including stock options, Board of Directors or other management positions.
 - Whether the campus has established a process for identifying, disclosing and managing institutional conflicts of interest.
- A judgmental sample of commercially and federally sponsored research awards active during fiscal year 2009-2010 were reviewed in order to verify that the disclosures were submitted in accordance with policy requirements and established campus processes.
- A judgmental sample of positive 700U or federal research disclosures filed during fiscal year 2009-2010 were reviewed to evaluate if established campus procedures for monitoring have been followed and to determine if there is evidence of review by the COI Independent Review Committee.

The scope of the review excluded UC Conflict of interest policies addressing disclosure requirements for UC designated officials, employee/vendor relationships, hiring of near relatives, patent and technology transfer and use of University resources, Health Sciences Compensation Plan outside income and any COI/COC policies related to the Senior Management Group. The period of the review is fiscal year 2009-2010. For COC forms, forms included those due November 1, 2010 which cover fiscal year 2009-2010; 700U and federal disclosure forms were reviewed for contracts or grants active during fiscal year 2009-2010. Fieldwork was completed in December 2010.

III. CONCLUSION

Based on work performed, internal controls surrounding the reporting of Research COI and COC reporting were generally in compliance with existing policies and reporting requirements. Specifically for COC reporting, we found that in general, departments are aware of the existing deadlines for submission of Annual Reports by applicable faculty. While some departments were found to have received the Annual Reports after the November 1, 2010 deadline, the majority of departments are adequately monitoring, tracking, and following up with their staff to ensure that all reports are received in a timely manner. All COC reporting is done on a self-reporting basis and disclosures must be reviewed by the Department Chairs; however review of reports does not have a deadline specified in APM-025 and some reports received had not been reviewed at the time of the audit.

Two areas of improvements were noted: 1) the campus has not established an Institutional Conflict of Interest Policy to manage financial conflicts of interest and meet accreditation requirements by the Association for the Accreditation for Human Research Protection Programs, Inc. (AAHRPP); and 2) the COIAC should define which actions recommended to faculty will be followed up to confirm respective faculty have properly addressed reported conflict of interest matters.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

A. Institutional Conflict of Interest Policy

There is not an established Institutional Conflict of Interest Policy.

AAHRPP now requires that an institutional conflict of interest policy be established as part of their accreditation. Written submission to AAHRPP for accreditation is due by March 15, 2011.

The Ethics and Compliance Office is aware of the need to develop an institutional conflict of interest policy and is currently working to determine what is necessary for policy development.

Without accreditation, all approved research for the San Francisco Veteran's Affairs Medical Center (SF VAMC) would be in jeopardy because the VA requires the AAHRPP accreditation. While the most significant impact would be at SF VAMC, it would also affect all UCSF researchers conducting studies at the SF VAMC. Other impacts could be increased scrutiny from regulatory agencies, potential difficulties with some sponsors, and negative public perception.

Management Corrective Actions

By March 15, 2011, the Ethics and Compliance Office will prepare a draft Institutional Conflict of Interest Policy for review by the Chancellor's Office, prior to submission to AAHRPP. Additionally, the COIAC will work with the Chancellor's Office to determine who will be responsible for the review of institutional conflicts when they arise.

B. Follow-up on Actions Recommended by COIAC

COIAC has not defined which actions are to be follow-up as part of their system for ensuring effective management of reported conflicts of interest.

When conflict of interest situations are reviewed by the COIAC, they issue a letter (i.e. Action Letter) to faculty which recommends actions to be taken. The recommended actions range from easy and straight forward to conditional and those which may take an extended period. The faculty member is required to sign the letter acknowledging their agreement to take action on the recommendations. Evidence of PI's signature on the Action Letter is considered to be an agreement to fulfill the conditions stated in the letter.

COIAC has a practice of following up on some actions to confirm the faculty member has mitigate the conflict of interest. However, COIAC does not have written policy defining which actions are to be followed up by the committee. Accordingly, there is not consistent follow-up.

Management Corrective Actions

By June 30, 2011, the COIAC will discuss and evaluate potential options for the follow-up of action items and will make recommendations to the Ethics and Compliance Office.

By September 20, 2011, the Ethics and Compliance Office will evaluate the recommendations given and determine the feasibility and best course of action to implement follow-up procedures on action items.

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