

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

**Conflict of Interest & Conflict of Commitment
Project #16-017**

December 2016

University of California
San Francisco



Audit and Advisory Services

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SUBJECT: Conflict of Interest & Conflict of Commitment Review 16-017

Audit and Advisory Services ("AAS") conducted a review surrounding conflicts of interest (COI) and conflicts of commitment (COC) to determine compliance with regulations and university policies on disclosures. Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the "IIA Standards").

Our review was completed in February 2016 and the preliminary draft report was provided to management in March 2016. Management provided us with their final comments and responses to our observations in December 2016. The observations and corrective actions have been discussed and agreed upon with department management and it is management's responsibility to implement the corrective actions stated in the report. In accordance with the University of California audit policy, AAS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Irene McGlynn', is written over a horizontal line.

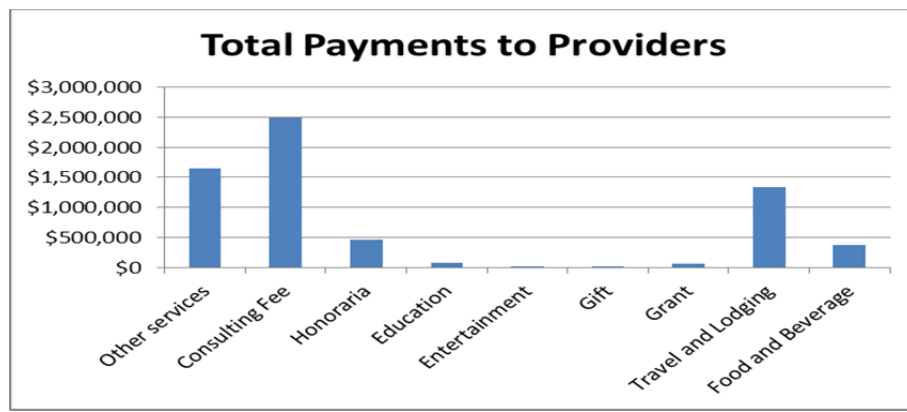
Irene McGlynn
Director
UCSF Audit and Advisory Services

I. BACKGROUND

Audit and Advisory Services (AAS) conducted a review of conflict of interest (COI) and conflict of commitment (COC). The purposes of the review were to perform data analysis to identify potential COIs and COCs and to assess compliance with regulations and university policies on disclosures.

Financial relationships between healthcare providers/researchers and private industry have received increased public scrutiny recently culminating in greater regulatory disclosure requirements. University of California, San Francisco (“UCSF” or “the University”) has internal policies on reporting outside professional activities and related income received from these activities.¹ At UCSF, the Office of Ethics & Compliance (OEC) has oversight responsibilities for COI specific to research activities, as regulated by Public Health Services and the California State Political Reform Act.²³ The Schools and department chairs have oversight responsibilities of outside activities and potential faculty COC. As part of this review, COI and COC disclosure processes were assessed for compliance with these external regulations and internal UC policies.

The Affordable Care Act charged the Centers for Medicare & Medicaid Services (CMS) with establishing a transparency program, known as Open Payments (OP). This program aims to increase public awareness of financial relationships between pharmaceutical/medical device manufacturers and health care providers. CMS published the first OP report in March 2013 and continues to publish annually. OP provides an independent data source for the University to corroborate disclosures made by providers and to identify potential COI and COC. Payments to UCSF providers for the period August 2013 – December 2014 as reported on the CMS OP system totaled \$6,451,951 and included the following types of payments (see figure below):



Other Services represents payments for services at non educational events

¹ APM 025 “Conflict of Commitment and Outside Activities of Faculty Members” and APM 671 “Conflicts of Commitment and Outside Activities of Health Science Compensation Plan Participants” provides guidance to general campus staff and faculty participating in the HS Compensation plan for the identification and management of outside professional activities in order to avoid conflicts of commitment. It also provides guidance on the accounting and depositing of income into the department compensation plan.

² 42 CFR Part 50, 94 “Responsibility for Promoting Objectivity in Research for which Public Health Funds is sought” requires disclosures of all significant financial interests meeting the threshold of \$5,000 or more for service payments and equity interests received from publicly and /non–publicly traded entities.

³ The California Code of Regulations, Title 2, §18755 requires disclosures at initial funding proposal and renewal of financial interests in private sponsors including income of \$500 or more in a 12 month period; investment/equity of at least \$2000; holding key management positions; gifts valued at \$50 or greater; and travel payments.

II. AUDIT PURPOSE AND SCOPE

The purposes of this review were to:

- Identify any faculty members' potential conflict of interest/commitment through data analytics;
- Determine faculty members' compliance with university policies on disclosures of conflict of interest/commitment; and
- Assess the adequacy of management oversight processes for managing conflict of interest/commitment.

Procedures performed for this review included extracting data from the CMS OP database, selecting providers who had high dollar payments as reported on the CMS OP website and received federal and private awards for verification of COI disclosures, assessing payments for compliance with the reporting requirements of outside professional activities (OPA) and the compensation plans reporting, and identifying opportunities for improvements. For more details on the test procedures performed, please refer to Appendix A.

The scope of the review covered transactions and activities for the period of August 2013 to December 2014 for selected School of Medicine (SOM) faculty members that met the criteria for our sample selection. Work performed was limited to the specific activities and procedures described in Appendix A. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in February 2016.

III. SUMMARY

UCSF's collaborations with pharmaceutical, biotechnology, and medical technology companies have brought benefits to the institution, including improved patient care, educational programs, and research activities. However, there are potential COI and/or COC risks involved as the University moves forward with its strategic goal to encourage innovation and entrepreneurship with private industry. These relationships need to be properly managed to ensure that decisions made regarding clinical care, research activities, and educational content are objective and not unduly influenced.

Based on work performed, we found multiple instances of non-compliance with policies and reporting requirements. The current COI and COC process is bifurcated with no assigned ownership or responsibility for overall oversight of the COI/COC compliance across the campus. The review indicated a need for a more coordinated and consistent approach among the campus units to provide clearer and consistent guidance to faculty on COI and COC activities and facilitate management and monitoring of such activities.

The specific observations from this review are listed below.

- There is a lack of clarity on policy requirements and coordination amongst the various campus units about how to facilitate the overall monitoring, oversight, and on-going education of COI and COC compliance requirements.

- Multiple instances of non-compliance with COI Federal/State regulations (42 CFR 50 / California Code Title 2, 18755) and University policies including APM025, APM671 and Industry Relations were identified.
- The University does not have an effective central reporting system to capture all types of financial interests, activities and relationships that may be subject to potential COI and COC.
- Annual disclosures of OPA are not completed in a timely manner and are not reviewed.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (“MCA”)

	Observations	Risk/Effect	Recommendation	MCA
1.	<p>There is a lack of clarity on policy requirements and coordination amongst the various campus units to facilitate the overall monitoring, oversight, and an on-going education of COI and COC compliance requirements.</p> <p>Multiple campus units have oversight responsibilities over COI and COC including the OEC, Academic Affairs, and Department Chairs, and Contracts and Grants (C&G). Each unit manages one component and advises faculty on their specific area. Thus, there is no mechanism for coordination between each unit to enable a holistic assessment of the faculty’s outside activities and relationships. Additionally, there is no central oversight coordinating body responsible for the overall oversight and coordination of COI/COC compliance on campus.</p> <p>Adding to the complexity is the lack of clarity in the University’s internal policies as well as Federal and State requirements. Faculty members and department management are required to understand and interpret numerous policies and regulations, some of which are quite complex, resulting in inconsistent interpretation and implementation of these policies.</p>	<p>It is more difficult to achieve compliance with a fragmented approach and lack of clarity on policy and reporting requirements and the likelihood of confusion and inconsistencies on interpretation of policies and regulations are increased. Additionally, compliance requirements cannot be reinforced without on-going training.</p>	<p>The University should consider creating a workgroup/committee that includes representatives from the OEC, Academic Affairs, C&G, ITA, and representatives from each School.</p> <p>The workgroup will serve as an advisory body and be charged with responsibilities such as the following:</p> <ul style="list-style-type: none"> • Define roles, responsibilities and accountability of each unit for coordination and oversight of COI and COC related matters • Ensure there is an appropriate mechanism in place to provide faculty with guidance and clarity on policies and procedures. • Identify an effective delivery approach and process for an ongoing training and education program. • Define a process for Schools to review externally published data and validate the accuracy and completeness of internally 	<p>a. Responsible Party: EVCP Office</p> <p>Target Completion Date: April 30, 2017</p> <p>Relevant key parties that have oversight responsibilities for various components of COI/COC will gather for a retreat meeting to discuss and evaluate existing processes and provide recommendations for enhancements to include the following areas:</p> <ul style="list-style-type: none"> • Defining roles, responsibilities and accountability of each unit for coordination and oversight of COI and COC related matters • Assessing the scope of the Conflict of Interest Advisory Committee (COIAC) to extend beyond research and to develop a process for follow-up on actions by the COIAC for known

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	<p>Below are some examples:</p> <ul style="list-style-type: none"> Reporting of OPA – noted instances of inconsistent interpretation by Chairs and faculty members of whether educational activities held at industry should be treated as Category II or III. If payment activities and its agreement are not independently reviewed, understood and consistently interpreted, then there is a risk of faculty members under reporting consulting activity to the compensation plan due to his/her categorization of category III versus category II. Disclosures in COI form or 700U – noted instances of inaccurate and incomplete disclosures. Royalty Payments – noted instances that faculty members did not realize the necessity of disclosing royalty agreements from prior UC employment to the Innovation, Technology and Alliances (ITA) Office to determine whether the University has an interest in product design and development. Although payments are not required to be disclosed in OPA, they are required to be disclosed for COI in 700U as compensation for private awards and online for federal awards. Meals and travel/lodging payments – noted instances when meals and travel/lodging payments were received 		<p>reported disclosures such as payments from companies for which faculty has an award with to identify potential conflicts, or meals payment without service to identify reportable gifts or income that were not disclosed.</p> <ul style="list-style-type: none"> Facilitate a coordinated approach with all the Schools in the development of a “help desk” type resource to answer questions that faculty/ staff may have regarding COC and potential COI that may impact institutional responsibilities outside research. Develop a process for follow-up on actions by the COI Advisory Committee for known conflicts of interests for research and assess the effectiveness of the recommendations for adequately managing the COI risks. 	<p>conflicts of interests and assess the effectiveness of the recommendations for adequately managing the COI risks.</p> <ul style="list-style-type: none"> Identifying an effective and coordinated delivery approach and process for an ongoing training and education program. Assessing the current mechanism for adequacy in providing the faculty with guidance and clarity on policies and procedures, including reporting of travel and meals. Defining a process for Schools to review and validate externally published data (such as CMS Open Payments) for accuracy and completeness of internally reported disclosures. Evaluating a structure that includes a central oversight coordinating body.

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	<p>without corresponding service payments such as consulting or honoraria fees, these could be construed as income or gifts under UCSF's Industry Relations Policy, which does not allow acceptance of free meals for attending an event and is reportable under federal and state conflict of interest disclosures.</p> <p>While there are resource materials posted on Office of Sponsored Research and OEC websites, the University does not have a comprehensive on-going education program to ensure compliance requirements are reinforced and faculty members are informed of the requirements relevant to the changing relationships and outside activities.</p>			<p>b. Responsible Party: Office of Ethics and Compliance Target Date: Completed</p> <p>Office of Ethics and Compliance has revisited the forms that the faculty uses to report financial conflict of interest in research, and deemed it sufficient to provide the guidance and information/education needed for faculty to understand and to report on financial conflict of interest in research related instances. Office of Ethics and Compliance will continue to encourage faculty to call their office as ad-hoc questions arise.</p> <p>c. Responsible Party: ITA Target Completion Date: March 31, 2017</p> <p>ITA will work with the Schools to communicate to faculty members on the importance of disclosures and review of royalty agreements by ITA.</p>

	Observations	Risk/Effect	Recommendation	MCA
2.	<p>Multiple instances of non-compliance with Federal/State and University policies were identified.</p> <p>We reviewed the records for 30 faculty members who received payments per the CMS Open Payment system and identified the following instances of non-compliance with policies and regulatory reporting requirements:</p> <p>a) Conflict of Interest:</p> <ul style="list-style-type: none"> • Five faculty members received compensation during the course of privately sponsored clinical studies in violation of Academic Senate Rule #11. • Seven faculty members have at least one instance of inaccurate or missing disclosures of financial interests for public and private sponsored research awards. <p>b) Outside Activities:</p> <ul style="list-style-type: none"> • Three faculty members have founding/co-founding roles in start-up companies, a Category I⁴ activity that had not been reported nor approved by the Chancellor. • Seven faculty members either did not disclose or under reported 	<p>Faculty member's failure to accurately report all financial interests limits the University's ability to meet its institutional responsibilities for oversight and management of COI and COC and could potentially create reputation risks.</p>	<p>a) SOM Academic Affairs in conjunction with the individual departments should consider whether further investigation is warranted for the non-compliant instances identified in the review.</p> <p>b) Faculty members should disclose existing royalty agreement if they have not done so and/or consult with ITA when there is a need to commercialize an invention or to enter into an agreement with outside companies (such as a royalty arrangement) to ensure that proper procedures are followed and the University's interests are protected.</p> <p>c) Faculty members need to review CMS OP data annually in April and work with respective Pharmaceuticals/ manufacturer to correct any inaccuracy and maintain records and supporting documents for direct and indirect payments and provide them upon request.</p> <p>d) Faculty members should reach out to SOM Academic Affairs to</p>	<p>a. Responsible Party: School of Medicine Academic Affairs and EVCP Academic Affairs</p> <p>Target Completion Date: February 2017</p> <p>Non-compliance instances of University's reporting/disclosure requirements will be forwarded to the SOM Academic Affairs for determination on whether any further actions are warranted. If further action is warranted, the information will be forwarded to EVCP Academic Affairs for academic misconduct process.</p> <p>Please refer to MCA for observation #1 pertaining to faculty training and education.</p>

⁴ Category I activities are outside professional activities that require significant professional commitment and include employment outside of the University; assuming a founding/co-founding role of a company, executive or managerial position and or teacher, research or administration of a grant at an organization outside of the University.

	Observations	Risk/Effect	Recommendation	MCA
	<p>outside activities and income to the departmental compensation plan.</p> <ul style="list-style-type: none"> One faculty had extensive conflict of commitment based on the Chair's assessment and remediation actions have been taken to prohibit further outside activities. <p>c) Industry Relations: One faculty member received payments to serve on the pharmaceutical speaker bureau.</p>		<p>make sure that appropriate reporting is completed for category I activity that had been identified as not reported or approved by the Chancellor.</p>	
<p>3.</p>	<p>The University does not have an effective central reporting system to capture all types of financial interests, activities and relationships that may have exposure to potential COI and COC.</p> <p>Currently there are disparate systems and methods for faculty to report financial interests and outside activities:</p> <ul style="list-style-type: none"> COI system collects financial interest information only for federal sponsored grants purposes. The California State's Statement of Economic Interest, a paper-based form 700U, is required for privately sponsored research. OPA and reporting of incomes for the Health Science Compensation plan are mainly paper-based and 	<p>With such disparate reporting methods, there are inefficiencies, duplication of reporting, and limits to the ability for monitoring, identifying anomalies, and providing meaningful reports.</p>	<p>The University should evaluate the feasibility of having a central reporting system that will foster communication and coordination across units and has the capacity and functionality to incorporate both COI and COC reporting.</p> <p>Until a system solution can be implemented, Office of Vice Provost, Academic Affairs and the Vice/Associate Deans-Academic Affairs in all of the Schools should provide guidance and increase its communication and education efforts reinforcing the need to fully and accurately report all outside activities.</p>	<p>a. Responsible Party: Office of Ethics and Compliance</p> <p>Target Completion Date: Completed</p> <p>Since the completion of the review, it has been established that the COI system under current evaluation will not be able to accommodate COC functionalities and therefore a decision has been made to proceed with a new COI system without accommodating COC related functionalities.</p> <p>b. Responsible Party: EVCP Academic Affairs</p>

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	<p>managed at the department level, although some departments such as the Department of Medicine have developed an internal electronic reporting system.</p>			<p>Target Completion Date: March 31, 2017</p> <p>Will work with other UC campuses to explore a multi-campus COC system that would facilitate policy compliance, training and connections with other University systems (e.g., COI).</p> <p>Decision on whether campus will pursue a multi-campus COC system will be made by March 31, 2017.</p> <p>If such a system is not pursued, other options will be explored with and by all Schools.</p>
<p>4.</p>	<p>Annual disclosures of OPA are not timely completed and reviewed.</p> <p>Annual outside disclosures are now processed through the Human Resources Service Center. Due to staffing constraints, some of the service centers have not sent the disclosures for Fiscal Year 2015 to the faculty for completion, thereby limiting the department administrators' ability to review and monitor compliance activities.</p>	<p>While departments are ultimately responsible for OPA compliance, it is difficult to identify, assess, and comply with internal policy when disclosure information is not collected and</p>	<p>Human Resources management should consider establishing a consistent tracking process to ensure that disclosure forms are distributed, completed and collected in a timely manner.</p>	<p>Responsible Party: Human Resources</p> <p>Target Completion Date: February 28, 2017</p> <p>Human Resources will develop consistent procedures across the service centers for the distribution and collection of OPA disclosure forms to</p>

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	Additionally, during our review, we identified cases where faculty members had not completed the outside activities disclosure form for Fiscal Year 2014, indicating a lack of an effective tracking process in place for ensuring that all disclosure forms are completed and submitted.	disseminated to department chairs for review in a timely manner.		include consistent language and deadlines for the call for OPA disclosures; three reminder alerts and a report to departments regarding faculty members that have not complied with the request(s).

Process Improvements

	Observation	Risk/Effect	Recommendation
1	<p><i>The current COI reporting requirement for privately sponsored grants may not necessarily identify all financial interests in a timely fashion.</i></p> <p>Form 700U is required to be completed by principal investigators at the initial award proposal stage and 30 days after renewal. Sponsored awards usually run for several years and potential COIs that may arise during the award period would not necessarily be captured, as there is no requirement to disclose each year.</p>	Potential COIs may go undetected during the active award period since there are no disclosure requirements.	For privately sponsored awards, consideration should be given to identify and establish a monitoring process in determining potential COIs that may arise during the course of the award period, particularly awards that span across multiple years.

	Observation	Risk/Effect	Recommendation
2	<p><i>There is no centralized process to review and monitor potential COI that fall outside of research activities.</i></p> <p>The scope of the COI Advisory Committee is limited to COI in research. Potential conflicts that arise as part of procurement of goods and services or when faculty members enter into consulting agreements are left to Supply Chain or department management, who may or may not have the requisite skills or knowledge required, to make determination on the conflict identified.</p>	<p>Inconsistent practices and ineffective monitoring or follow-up of COI can arise</p>	<p>a) Management should consider developing a structure for review and management of COI outside of research activities. The scope of the COIAC will be evaluated as part of the overall assessment of COI/COC at the University – see MCA # 1A.</p> <p>b) Department management and/or Purchasing should consider reviewing CMS OP as a source of information to identify faculty members with potential COI who may influence decision making in the procurement process.</p>

APPENDIX A – Test Procedures

To conduct our review, the following procedures were performed for the areas in scope:

1. Reviewed relevant University policies and procedures on COI/COC reporting requirements.
2. Identified internal and external data sources to develop a risk profile of providers with potential COI and COC for detailed review including.
 - a) CMS OP to identify UCSF providers population and payments;
 - b) Personnel & Payroll system to identify employee ID, active status, and department;
 - c) Research Administration System to identify awards type and start/end date; and
 - d) Procurement to identify any correlation of vendor payments to pharmaceutical and device manufacturers to identify payments made to physicians.
3. Analyzed data and interviewed relevant personnel to determine whether a COI and COC exist.
4. For selected sample, requested Department Chairs to coordinate with faculty members to assess and determine whether payments from industry per CMS OP were disclosed and these disclosures were in compliance with University policies.
5. Assessed compliance with policy on disclosure of COI/COC.