**Internal Audit Report**

# Conflict of Interest Disclosures in Research

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James Dougherty
Principal Auditor

**Approved**
Barry Long, Director
Audit & Management Advisory Services

UC SANTA CRUZ

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## I.    EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed an audit of conflict of interest in research (COIR) disclosures to evaluate the controls in place to help ensure disclosures comply with relevant policies and regulations.

Overall, controls established by the Office of Research and campus offices provided reasonable assurance that principal investigators were informed of their responsibility to disclose potential or actual conflicts of interest in a timely manner as required by research sponsors or by policy. Practices in place included the vetting of positive disclosures applying published thresholds and an evaluation by the campus Independent Substantive Review Committee. In addition, practices included that Committee recommendations are forwarded to the vice chancellor for Research (VCR) for a final determination; and a requirement that once principal investigators agree to management plans and address recommendations, funds are released to the sponsored project.

However, opportunities were identified to enhance controls that researchers complete the COIR training before they begin research funded by the Public Health Service in compliance with that federal agency's requirements; for formalizing and establishing timely implementation of COIR management plans; and for ensuring that funds were not released until a management plan to address a conflict of interest has been completed.

The following observations requiring management corrective action were identified:

> **A.   Training for Conflict of Interest in Research Disclosures**
> Controls could be enhanced to ensure researchers complete required training before beginning research on PHS-funded projects.
>
> **B.   Verification of the Implementation of COI Management Plans**
> The Campus did not have standard follow-up procedures to verify that investigators had implemented conflict of interest management plans as agreed.
>
> **C.   OSP Release of Awards**
> An OSP contract and grant officer released award funds to an investigator before receiving confirmation that the investigator agreed to the conflict of interest management plan.

Management agreed to all corrective actions recommended to address risks identified in these areas. Observations and related management corrective actions are described in greater detail in section III. Of this report.

## II.    INTRODUCTION

### Purpose

The purpose of the audit was to evaluate the controls in place to help ensure disclosures comply with relevant policies and regulations.

### Background

The following highlights were printed in an article published by the Hastings Center entitled "Conflict of Interest in Biomedical Research":

> *Financial relationships can create conflicts of interest between researchers' obligations to abide by scientific and ethical principles and their desire for financial gain.*
>
> *The risk, therefore, is that conflicts could adversely affect the quality of research, possibly harming human subjects and patients along with public trust in the biomedical research enterprise.*
>
> *However, financial relationships with industry also carry benefits, including facilitating the development of new drugs and medical devices and increasing research budgets and opportunities.[1]*

The risk that conflicts of interest could undermine trust in research is not limited to biomedical research. Research sponsors may require disclosure and management of conflicts of interest to provide reasonable assurance that their sponsored research will be conducted free of bias. Consequently, the University of California has several policies that address it:

- APM – 028 -- Policy on Disclosure of Financial Interest in Private Sponsors of Research
- Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards
- Disclosure of Financial Interest & Management of Conflicts of Interest, Public Health Services Research Awards

While researchers are mainly responsible for complying with these policies, campus offices, especially the Office of Research, provide procedures to help ensure compliance.

Research sponsorship comes in the form of contracts and grants, administered by the Office of Sponsored Projects, and gifts, administered by Gift Administration. Potentially, should conflict of interest (COI) issues occur during licensing agreements the Intellectual Property Office would handle them.

These offices are responsible for ensuring that investigators[2] are aware of COI disclosure requirements and establishing practices that help ensure that researchers fill out COI disclosures when required by sponsors or by policy. Positive disclosures are sent to the Office of Research Compliance Administration (ORCA) where they are vetted according to policy threshold standards for potential or actual conflicts of interest.

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[1] thehastingscenter.org/briefingbook/conflict-of-interest-in-biomedical-research/

[2] An investigator is any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project. This includes the principal investigator, co-investigators, and any other individual who has responsibility for designing, conducting, or reporting of research funded by the sponsor or proposed for such funding.

Disclosures that meet these thresholds are then reviewed by the Independent Substantive Review Committee (ISRC) to identify options on how to respond to the conflict of interest – manage or eliminate it – and make recommendations to the vice chancellor for Research (VCR), who provides the final decision on how to respond.

From July 1, 2015, to December 31, 2016, the Office of Sponsored Projects (OSP) administered 1,644 awards, 170 of which required COI disclosures and sent 34 positive disclosures to ORCA. Gift Administration sent three to ORCA. ORCA vetted these positive disclosures of which five were reviewed by the ISRC.

## Scope

The scope of our review included research conflict of interest disclosure practices during FY2016 to December 2016. Our review included meetings with management, examination of policies, procedures, and other related documents, reviews by the Independent Substantive Review Committee, and a previous, system-wide audit we conducted on this topic. Specifically, we

- Learned COI disclosure practices of the Office of Research through discussions with the assistant VCR, Research Administration & Compliance, the director of Office of Research Compliance Administration, the director of the OSP, and the technology licensing officer of the Industry Alliances & Technology Commercialization Office

- Learned Gift Administration COI disclosure practices from the manager of Gift Administration

- Reviewed the UC policies pertaining to COI in research, namely:

    o Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards (this policy applies to requirements of the federal Public Health Service (PHS), including sub-agencies, e.g. NIH, and other non-federal research sponsors who have adopted this policy)

    o Disclosure of Financial interest and Management of Conflicts of Interest, National Science Foundation (NSF) Awards (this policy applies to other sponsors that have adopted the NSF policy)

    o UC Academic Personnel Manual 028 University Policy on Disclosure of Financial Interest in Private Sponsors of Research

    o The UC Conflict of Interest Code that addresses the requirements of the California Political Reform Act, including academic decisions

- Discussed the campus interpretation of relevant UC policies with the director of Research Policy Development, UCOP, and the COI coordinator, UCOP

- Discussed with Ethics, Compliance and Audit Services, UCOP, the method used to update the learning management system with the audience for COIR training

- Reviewed a previous system-wide audit that addressed this subject, namely, Conflict of Interest and Conflict of Commitment, SC-11-02, December 2010

- Obtained an account for the contract and grant management system, Cayuse, used by OSP, so that we could identify the proposals and awards that required COI disclosures during the scope of our review

- Learned how the Independent Substantive Review Committee (ISRC) operates from the chair of that Committee

- Reviewed documentation associated with all the reviews by the ISRC during the scope of this audit

## III.    OBSERVATIONS REQUIRING MANAGEMENT CORRECTIVE ACTION

| A. | Training for Conflict of Interest in Research |
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Controls could be enhanced to ensure researchers complete required training before beginning research on PHS-funded projects.

**Risk Statement/Effect**

Non-compliance with the federal Public Health Service/NIH requirements for grant funding could entail sanctions affecting campus research projects.

**Agreement**

| A.01 | The ORCA will establish a procedure to periodically review training records to help ensure compliance with funding agency training requirements and implement this procedure. | Implementation Date |
|---|---|---|
| | | 09/30/2017 |
| | | Responsible Manager |
| | | Director, ORCA |

**A. Training for Conflict of Interest in Research – Detailed Discussion**

The Code of Federal Regulations states the following requirements:

*Title 42 Public Health, Chapter I, Subchapter D, Part 50 Policies of General Applicability*

*§50.604   Responsibilities of Institutions regarding Investigator financial conflicts of interest.*

*Each Institution shall:*

*(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:*

*1)   The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;*
*2)   An Investigator is new to an Institution; or*

3) *An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.*

The UC Policy on the Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards, Section III.G "Training" states:

*Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by the University in accordance with DHHS (Department of Health and Human Services) regulations. For PHS-funded Investigators who are new to the campus or who are joining an ongoing PHS Research Activity, the campus should establish a reasonable, expeditious timeframe when Investigators must complete training.*

The UCSC UC Learning Center (Learning Center) provides training in conflict of interest in research (COIR). UCOP updates the training every four years and it provides a list of researchers who require this training to feed into the learning management system (LMS) every two years.  Although UCOP usually sends the list in the fall, based on year-end data from the corporate payroll system, it sent the most recent list in January 2017 due to updating the training.  Consequently, an investigator who receives a PHS-funded award may not receive notification timely by the Learning Center that they must take this training.

OSP contract and grant officers ensure that investigators who receive a PHS award must complete a form (Form 900D) to disclose their financial interests and also certify that they understand that they must complete a UCSC COI training session prior to participating in research related to any PHS-funded project.  Their response provides an honor system-based assurance, but an additional control of periodically auditing training records would provide further assurance that these investigators have taken the training as required.

| B. | Verification of the Implementation of COI Management Plans |
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The Campus did not have standard follow-up procedures to verify that investigators had implemented conflict of interest management plans as agreed.

**Risk Statement/Effect**

Sponsors may suspend or terminate the award and/or debar an investigator from receiving future awards in the event of failure to comply with applicable funding agency requirements on disclosure, review, and management of significant financial interests related to sponsored projects.

**Agreement**

| B.01 | The Office of Research Compliance Administration will establish a verification procedure to ensure that COI management plans are implemented as agreed. | Implementation Date |
|---|---|---|
| | | 03/31/2018 |
| | | Responsible Manager |
| | | Director, ORCA |

| B. Verification of the Implementation of COI Management Plans. – Detailed Discussion |
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The ISRC is charged with the responsibility to review positive COI disclosures in research that meet thresholds identified by policies. Based on its review, it makes recommendations to the VCR that the project should not proceed or that it may proceed under conditions to manage the COI. Examples of conditions or restrictions included in such a management plan may include:

- Public disclosure of the related financial interest(s), including notice of the interest as an addendum to all publications arising from the project
- Monitoring of the project by independent reviewers
- Modification of the research or project plan
- Disqualification from participation in all or a portion of the project
- Divestiture of the related financial interest(s)
- Severance of relationships that create actual or potential conflicts

The VCR decides on the COI management plan and informs the investigator, who must agree with the plan in order to obtain funds from the sponsor and proceed with the project. The ISRC relies on the honor system for the investigator to implement his or her agreement. However, it may request evidence that the investigator has implemented the management plan. We observed this in one case where an NIH-sponsored project was undergoing an annual review. The NIH requires annual COI disclosures even if no new conflicts of interest have arisen for a multiple year project. The NSF does not have such a disclosure requirement.

In that particular case, because a verification procedure was not a standard practice by the ISRC or the ORCA, and the PI was late in responding, verification was obtained late in the review process.

The UC Policy on the Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards, Section III.D "Monitoring" states:

> *The management plan put in place by the campus shall specify the way in which the Investigator's compliance with the management will be monitored on an ongoing basis until completion of the PHS-funded research project.*

In our opinion, the ORCA should establish a verification procedure, also known as a follow-up procedure, to ensure COI management plans are implemented as agreed timely. This should apply to all management plans not just PHS-related annual disclosures.

A follow-up procedure would require some changes to COI management plan procedures, specifically that the investigator includes an implementation date for those parts of the plan that can be scheduled. Further, ORCA would need a system to keep track of those dates and sufficient staff to carry out the follow-up procedures, such as requesting investigators for evidence of implementation, and procedures for raising issues of not fulfilling agreements with a higher level of management, such as the VCR, to help ensure implementation of the management plan.

| C. | OSP Release of Awards | | |
|---|---|---|---|
| An OSP contract and grant officer released award funds to an investigator before receiving confirmation that the investigator agreed to the COI management plan. | | | |
| **Risk Statement/Effect** | | | |
| Sponsors may suspend or terminate the award and/or debar an investigator from receiving future awards in the event of failure to comply with applicable funding agency requirements on disclosure, review, and management of significant financial interests related to sponsored projects. | | | |
| **Agreements** | | | |
| **C.01** | The Office of Sponsored Projects has informed contract and grant officers of the importance of not releasing award funds to projects until a COI management plan has been approved by the VCR and agreed to by the investigator, and establish a protocol to ensure that funds are not released. | Implementation Date | |
| | | 04/15/2017 | |
| | | Responsible Manager | |
| | | Director, OSP | |
| **C.02** | The Office of Research Compliance and Administration will establish a protocol ensuring that OSP contract and grant officers are notified timely when the investigator agrees to a COI management plan. | Implementation Date | |
| | | 03/31/2018 | |
| | | Responsible Manager | |
| | | Director, ORCA | |

| C. OSP Release of Awards – Detailed Discussion |
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Research sponsors, such as the NSF and the PHS, have requirements regarding the review and management of significant financial interests related to sponsored projects. Such reviews need to be conducted and management plans adopted before award funds are released to investigators.

The UC Policy on the Disclosure of Financial interest and Management of Conflicts of Interest, National Science Foundation Awards, Section VI "Review of Disclosures" states:

> *Reviews must be completed and any identified conflicts of interest must be managed, reduced or eliminated prior to the institution's expenditure of funds under the award.*

The UC Policy on the Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards, Section III.B "Review of Disclosures; Management Plan" states:

> *The management plan is to be implemented prior to the University's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest*

Consequently, OSP has procedures and a checklist that contract and grant (C&G) officers use to ensure that COI management plans are approved and agreed to before releasing the award to the investigator. We observed in one case where an award was released by a C&G officer before the management plan was approved and agreed to. There is reason to believe this was exceptional due to the difficulty that the ORCA had in locating the investigator for that project and getting his response timely to the ISRC's request for verification of a management plan agreement; this was referred to in Observation B.

Further, we observed that C&G officers were notified of approved COI management plans by being copied on the email sent by ORCA to investigators; we did not see a notification to these officers that the investigators had agreed to the plan. Therefore, we believe the ORCA could improve its communication to OSP of the investigator's acceptance of the management plan to ensure that funds are not released until that acceptance occurs.

## APPENDIX - Summary of Work Performed and Results

| Preliminary Survey and Risk Analysis | |
|---|---|
| **Work Performed** | **Results** |
| • We conducted a preliminary survey to identify the objective of relevant campus offices concerning COI in research disclosures; risks that affected the achievement of those objectives; controls in place to eliminate or manage those risks; residual risks; and an assessment of those risks to determine if further controls would be helpful on a cost/benefit analysis. | The Office of Sponsored Projects has procedures to not release a proposal unless it has received required COI disclosures from investigators. Investigators will not receive awards unless they have filed required disclosures. These are controls to ensure that required disclosures are made. Gift Administration also requires investigators who receive research gifts to fill out COI disclosures before they can receive these gift funds.<br><br>The Industry Alliances & Technology Commercialization Office requires researchers who have not disqualified themselves from being involved in the decision of what licensees would get a license for their invention are required to fill out COI disclosures.<br><br>Positive disclosures are sent by these offices to the Office of Research Compliance Administration and are vetted according to threshold requirements. Those disclosures with supporting documents are then provided by the ORCA to the Independent Substantive Review Committee for review and recommendations – manage or eliminate it – and the vice chancellor for Research provides the final decision on how to respond. Upon agreement to this decision by the investigator, OSP releases awards to the project. These procedures are fairly straightforward and give the impression of reasonable controls of the COI disclosure process.<br><br>However, there were concerns about<br>• the campus interpretation of time of NSF disclosure, particularly the potential for an annual disclosure renewal;<br>• how the review of positive COI disclosures takes place to ensure it is reasonable; and<br>• the Cayuse contract and grant management system to ensure disclosure requirements are managed adequately with this system. |

| Timing of NSF COI Disclosures | |
| --- | --- |
| **Work Performed** | **Results** |
| • We reviewed OSP procedures for obtaining COI disclosures for NSF-sponsored projects.<br><br>• We reviewed UC COI Disclosure Policy for NSF Awards<br><br>• We discussed the interpretation of that policy with the director of Research Policy Development, UCOP, and the COI coordinator, UCOP | Our discussions with UCOP officials resulted in our conclusion that OSP procedures regarding COI disclosures for NSF-funded projects were in compliance with UC policy.<br><br>Further, we learned that Public Health Services does not always verify that COI management plans are approved and agreed to before providing award funds to the Campus for release to projects. This emphasizes the need for the Campus to implement adequate procedures to ensure such plans are approved and agreed to before releasing the funds. |

| Review of Positive COI Disclosures | |
| --- | --- |
| **Work Performed** | **Results** |
| • We interviewed the chair of the ISRC to learn how the Committee operated.<br><br>• We reviewed the procedures used by ORCA to conduct the process of review of positive COI disclosures.<br><br>• We obtained a report from OSP on proposals and awards during our scope that required COI disclosures.<br><br>• We obtained for analysis documents of cases reviewed by the ISRC from ORCA.<br><br>• We discussed our observations with the directors of OSP and ORCA. | Procedures for reviewing positive COI disclosures by the ISRC were adequate for the most part.<br>The ISRC conducted its review adequately of the five cases that occurred during the scope of our audit. There were opportunities for improvement identified in section III. |

| The Cayuse System for COI Disclosure Management | |
| --- | --- |
| **Work Performed** | **Results** |
| • We discussed the Cayuse system with OSP management in its usefulness regarding COI disclosures.<br><br>• We requested OSP for a report on positive COI disclosures it obtained and passed on to ORCA. | Cayuse does not have a COI box to check at award processing (only at proposal time), nor is there an alert (OSP had set one up when we used FileMaker). OSP was delayed in providing us with the report we requested because it discovered that the Cayuse developer made a mistake by not linking the fields to the COI questions. OSP notified the developer, who fixed it in time for us to obtain the information we sought for this review. |

| Timing of COIR training | |
| --- | --- |
| **Work Performed** | **Results** |
| <ul><li>We contacted the analyst at Ethics, Compliance and Audit Services (ECAS), UCOP, to learn the procedure she uses for automatically updating the audience for COIR training in the learning management system (LMS).</li><li>We contacted the system-wide deputy compliance officer, ECAS, about limitations of the method used to update the audience for the COIR in the LMS.</li><li>We contacted the UCSC administrator of the UC Learning Center about the COIR training audience automatic feed from UCOP and the possibility for entering names into this audience manually.</li><li>We reviewed 900D Financial Disclosure Form</li><li>We tested if OSP requires investigators who work on PHS-funded projects to fill out Form 900D. We did this by identifying positive disclosures during FY16 and requesting OSP for the corresponding 900D forms</li></ul> | <ul><li>The list of names to enter in the LMS for COIR training is drawn from the corporate payroll system database at the end of fiscal close to identify all those who were paid out of extramural funds. However, there are no codes that identify personnel as researchers, therefore, they are not entered into the system as soon as they become researchers. The upload of names into the system occurs approximately every two years, and the training is updated every four years.</li><li>He was aware that the current schedule of COIR training audience feeds to the LMS may not be in time to ensure that researchers do not begin work on NIH-funded research projects before they receive the training. He said campuses re expected to determine training needs of researchers and manually enter their names in the LMS if needed to ensure timely training.</li><li>He received the current list of 407 names added to the COIR training audience is January. Normally he receives it every two years in the fall, after fiscal close, but a delay occurred this fiscal year due to updating the training, which occurs every four years. He can manually enter names into the COIR training audience if requested.</li><li>Form 900D is provided by OSP to investigators who receive PHS funding. It requires investigators to certify that they understand that they must take the UCSC COIR training before working on PHS-funded projects. This provides an honor system-based assurance that could be enhanced with a periodic review of training records to ensure compliance with PHS training requirements. Our testing verified that OSP requires investigators on PHS-funded projects to fill out Form 900D.</li></ul> |

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