

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

**Research Partnerships**

**Project #18-029**

**May 2018**

University of California  
San Francisco



**Audit and Advisory Services**

May 31, 2018

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**SUBJECT: Research Partnerships (Project #18-029)**

As a planned internal audit for Fiscal Year 2018, Audit and Advisory Services (“A&AS”) conducted a review of research partnerships. The purpose of this review was to assess the processes and controls over the management and oversight of UCSF’s research partnerships with private industry.

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 March 2018 and the preliminary draft report was provided to department management in April 2018. Management provided us with their final comments and responses to our observations in May 2018. 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, A&AS 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 light blue horizontal line.

Irene McGlynn  
Director  
UCSF Audit and Advisory Services

## EXECUTIVE SUMMARY

### I. BACKGROUND

As a planned audit for Fiscal Year 2018, UCSF Audit & Advisory Services (A&AS) completed a review of selected research partnerships with private, for-profit entities. UCSF enters into various collaborative research partnerships with private, for-profit entities to further its mission of research discovery to cure disease and advance healthcare worldwide. The intent of these partnerships is for UCSF researchers to apply their scientific knowledge and expertise to areas of interest for private sector partners, including, but not limited to potential innovative drug therapies. The process for establishing these partnerships is jointly led by UCSF Innovation Ventures (IV) and UCSF Office of Sponsored Research, Industry Contracts Division (ICD). Ensuring that adequate procedures and processes are in place for effective administration of these research partnerships is important for building trusting collaborative relationships and ensuring future funding streams.

Partnership agreements can be initiated either by UCSF faculty members or by external partners with assistance from Innovation Ventures and ICD. Agreements are reviewed and approved by ICD within the Office of Sponsored Research (OSR). These agreements are subject to similar procedures and requirements as those for other externally supported research. One key difference is the negotiation of a Master Collaboration Agreement (MCA) that defines operational and administrative terms and conditions for activities conducted as part of the collaboration. After the MCA is established, individual research project agreements are executed under the MCA to include specific statements of work, budgets, and other project-specific items.

Once the collaborations are established, they are typically monitored jointly by UCSF and its industry partner under a governance or oversight committee (as defined in each individual agreement), with responsibility for local oversight provided at UCSF by Principal Investigators (PIs) and alliance managers. Requirements for notifying each partner of any invention discovery and licensing and other intellectual property arrangements are governed by the terms of the MCA. Terms also exist around provisions for human and animal test subjects, reporting of interim progress and final results, and requests to publish or present the results of any ongoing or completed research.

### II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess the processes and controls over the management and oversight of UCSF's research partnerships with private industry. Specific processes and controls reviewed related to compliance with key terms of the MCAs, compliance with institutional policies and procedures related to research and intellectual property, and appropriate use of University resources related to project scope and access to/use of facilities.

Three projects (one associated with each of three separate partnership Master Collaboration Agreements) were selected for this review. Where referenced in this report, they are identified as projects A123940, A124551, and A120595 in conjunction with the designated UCSF award number for each. The Master Collaboration

Agreement for Project A123940 was executed in 2013 and the associated project, also initiated in 2013, involved studies to test inhibition of fibrosis in the kidney and liver. The Master Collaboration Agreement for Project A124551 was executed in 2013 and the associated project, initiated in 2014, supports studies regarding the inhibition of genes associated with the proliferation of certain types of brain tumors. Finally, the Master Collaboration Agreement for Project A120595, executed in 2011, was associated with a project begun in 2012 focusing on a potential treatment for patients with multiple myeloma.

Procedures performed as part of the review included: reviewing research agreements and related documentation, interviewing administrative and research personnel associated with the research and project administration, and analyzing data recorded in the University's financial and other systems. Fieldwork was completed in March 2018. For more detailed steps, please refer to Appendix A.

Work performed was limited to the specific activities and procedures described above and in Appendix A. As a result, this report is not intended to and cannot be relied upon to provide an assessment of compliance beyond those areas specifically reviewed.

### III. SUMMARY

Based on work performed, we identified the following areas where process and controls improvements are recommended in order to mitigate potential adverse effects:

- Business practices did not always align with certain terms in the selected agreements;
- The process for identifying and disposing of materials provided by the research partners is not consistent;
- Invoices to the project sponsor for payment were not always submitted timely, per project agreement terms and milestones; and
- Project agreement renewals were not always executed prior to the end of the previous award period.

Further details on specific observations and management corrective actions are set out in Section IV, "Observations and Management Corrective Actions ("MCA")".

Additional opportunities for process improvements are suggested in the area of partnership agreement template language. These suggestions are further detailed in Section V, "Opportunities for Improvement".

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

<u>No</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
1.	<p><b><i>Business practices did not always align with certain terms in the selected agreements.</i></b></p> <p>Our review of compliance with agreement terms identified instances where UCSF’s practices did not align with the terms of selected agreements as follows:</p> <p>a) submitting publications for review by the prescribed deadline</p> <p>The partnership agreements require UCSF to submit any publication manuscript to the partner for review either 30 or 60 days (depending on the agreement) prior to the proposed date of submission for publication. In the case of Project A123940, we identified 1 of 5 requests that did not meet this deadline. For requests related to Project A120595, data was unavailable but we were told that the deadline was not always met.</p> <p>b) prior approval for animal studies</p> <p>Project A123940 required that “any project involving animal use will be reviewed and granted approval by [the partner’s] Global Animal Welfare</p>	<p>Agreement terms are negotiated to document the partnership requirements that each party agrees to and to ensure both parties’ risks are appropriately covered. Not following certain terms of agreements may potentially expose the University to legal or other liabilities related to non-compliance and could discourage a partner from entering into future collaboration agreements.</p>	<p>1.1. To facilitate awareness among all project personnel, important agreement terms should be summarized and shared with all project personnel, including changes due to award extensions and other amendments.</p> <p>1.2. UCSF should ensure that any desired terms are incorporated into agreements and amend agreements to remove terms once they are no longer necessary or relevant.</p>	<p><b>Action:</b> Alliance Managers will ensure that project alliance meetings with UCSF researchers highlight all key compliance terms.</p> <p><b>Responsible Party:</b> Director, Office of Strategic Alliances</p> <p><b>Target Date:</b> December 28, 2018</p> <p><b>Action:</b> Contracting officers will ensure that future agreements include terms allowing for additional flexibility in determining the need for written reports and scheduling of oversight meetings where other communication channels are available to relay the intended information between the partners. Terms should also allow for changes to be approved by email or other correspondence in lieu of issuing an amendment.</p>

<u>No</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
	<p>Committee before animal work can begin.” While UCSF’s Institutional Animal Care and Use Committee (IACUC) approved the study, we saw no documentation of the partner’s approval.</p> <p>c) submission of written progress reports did not always occur</p> <p>Each of the selected agreements required UCSF to provide interim progress reports throughout the life of the project. Projects A124551 and A120595 specified that written reports were to be submitted on a set schedule; Project A123940 required “communications, reports, and data as reasonably requested” with a written report only due at the conclusion of the project, which was provided.</p> <p>In discussions with the respective Alliance managers, it was indicated that formal reports were not typically submitted, but that project progress was communicated between UCSF and the partner during regular recurring project meetings, annual Steering Committee meetings, or upon request.</p>			<p><b>Responsible Party:</b> Director, Office of Sponsored Research, Industry Contracts Division</p> <p><b>Target Date:</b> July 31, 2018</p>

<u>No</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
	<p>d) meetings of the joint steering governance committees did not always occur according to the proposed schedule</p> <p>Each agreement established a governance group for UCSF and the partner to jointly monitor the collaboration. Meetings were set to occur either 2 or 4 times per year (depending on the agreement). Documentation we reviewed indicated that these collaboration governance meetings were either held less frequently or not at all.</p> <p>The primary causes for non-alignment with agreement terms were: (1) lack of knowledge that the requirement existed and (2) reliance on an understanding with the partner that a more informal approach than that specified in the agreement was acceptable.</p>			
<p><b>2.</b></p>	<p><b><i>The process for identifying and disposing of materials provided by the research partners is not consistent.</i></b></p> <p>The process for identifying (through labels or other obvious markings) and accounting for provided materials appears inconsistent and highly dependent on the processes</p>	<p>If provided materials, which represent intellectual property belonging to the partner, are not appropriately identified and accounted for while in its custody, the University may increase its exposure to claims of improper use of these materials (e.g. use</p>	<p>2.1. Materials provided by research partners should be clearly labeled as such (including identifying information such as the partner name, nature of materials, etc.) so that they can be easily identified by any individual with access to the facility where the</p>	<p><b>Action:</b> The Associate Vice Chancellor, Research Infrastructure and Operations, will ensure that guidance about materials identification is communicated to researchers.</p>

<u>No</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
	<p>used by individual researchers in their own research facilities.</p> <p>During the course of our review, we observed provided materials with non-obvious labels/markings maintained in shared storage areas. We also observed materials still on hand (instead of being returned or disposed of) for projects that were completed.</p> <p>The partnership agreements typically require provided materials still on hand at the conclusion of a project to be either returned to the provider or destroyed.</p>	<p>outside the approved project).</p>	<p>materials are stored and disposed of appropriately at the conclusion of the project.</p>	<p><b>Responsible Party:</b> Associate Vice Chancellor, Research Infrastructure and Operations</p> <p><b>Target Date:</b> November 30, 2018</p>
<p>3.</p>	<p><b><i>Invoices to the project sponsor for payment were not always submitted timely, per project agreement terms and milestones.</i></b></p> <p>For the projects reviewed, billing amount and milestone dates were specified in the project agreements. Although agreement billing terms usually allowed for submission of quarterly invoices to the partner within 30-60 days after the end of a project quarter, several invoices were submitted more than 60 days after the end of the period. The longest identified delay for an invoice was 294 days. In several cases,</p>	<p>Submitting invoices for payment later than scheduled will delay the receipt of payment from the partner, requiring other sources of cash to support any expenditures incurred prior to payment as well as reducing cash available to support other projects.</p>	<p>3.1. Consideration should be given to maximizing the use of the Research Administration System (RAS) milestone alert feature or maintain a separate billing calendar system as a reminder to invoice according to the schedule of milestones laid out in the agreement.</p>	<p><b>Action:</b> Alliance managers will collaborate with the Executive Vice Chancellor &amp; Provost's Business Services Office to identify possible improvements in the current billing process.</p> <p><b>Responsible Party:</b> Director, Office of Strategic Alliances</p> <p><b>Target Date:</b> December 28, 2018</p>

<u>No</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>MCA</u>
	<p>multiple quarters were billed on the same invoice. We also identified invoices that were only issued semiannually or annually instead of quarterly. In some cases, invoices were delayed because the associated project agreement renewals had not yet been executed (see Observation #4, below).</p>			
<p><b>4.</b></p>	<p><b><i>Project agreement renewals were not always executed prior to the end of the previous award period.</i></b></p> <p>Four of the 17 (24%) project agreements reviewed that extended the performance period (i.e. renewals) had an effective date more than 30 days after the end of the prior award period. The lapse of time ranged from 39 to 242 days.</p> <p>According to UCSF contracting and liaison personnel, delays in executing project extensions are common and can include issues on the partner’s side, which cannot be resolved exclusively by UCSF.</p>	<p>If UCSF incurs obligations before receiving a sponsor’s commitment of financial support, those expenses may need to be paid for using departmental funding. Additionally, invoices cannot be submitted to the partner for payment until the agreement is in place (see Observation #3, above).</p>	<p>4.1 Continue efforts to ensure timeliness of UCSF renewal requests by establishing an internal deadline for submitting renewal requests to the partner prior to expiration of an existing performance period. Also consider establishing an escalation process when partners are non-responsive to requests.</p>	<p><b>Action:</b> The Office of Strategic Alliances will develop a protocol for ensuring that agreement renewals are submitted for approval and that any issues in the award process are escalated as appropriate within the context of maintaining positive partner relations.</p> <p><b>Responsible Party:</b> Director, Office of Strategic Alliances</p> <p><b>Target Date:</b> December 28, 2018</p>

**IV. OPPORTUNITIES FOR IMPROVEMENT**

No	Observation	Risk/Effect	Recommendations
1.	<p><b><i>Inconsistencies were identified between UCSF boilerplate template and executed partnership agreements that may or may not be advantageous for UCSF.</i></b></p> <p>UCSF maintains a boilerplate document of terms used to begin negotiations with industry partners, and these may be altered during negotiations leading up to the final agreement.</p> <p>Inconsistencies that were identified between the boilerplate and the selected agreements are in each of the following areas:</p> <ul style="list-style-type: none"> <li>• Agreement terms that appear to be less advantageous to or impose additional requirements on UCSF (for example, longer publication review deadlines, additional restrictions on intellectual property licensing, and notification of suspension/debarment proceedings against UCSF personnel beyond those participating in the sponsored research agreement)</li> <li>• Terms that were found only in the agreement and benefit UCSF or that are examples of good controls that may be considered for inclusion in the UCSF boilerplate to serve as a starting point for future agreement negotiations</li> </ul> <p>A listing of these items has been provided separately to management for consideration.</p>	<p>Terms that are less advantageous or impose additional requirements on UCSF may result in additional resources expended to meet those obligations or in failure to comply, which could impact future negotiations with industry partners.</p>	<p>1.1. Review suggested additions to boilerplate (listing provided to management) and consider incorporating these as appropriate.</p>

**APPENDIX A**

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

- Reviewed UCSF internal guidance regarding establishment of industry partnership agreements as well as sponsored agreements in general;
- Reviewed master collaboration and project agreements and related documentation for selected partnership agreements, and identified key agreement terms;
- Interviewed various UCSF personnel, including alliance managers, research investigators, and award administrators;
- Reviewed documents related to collaboration and project agreement oversight as well as interim and final progress reports;
- Reviewed UCSF internal documentation regarding animal welfare laboratory accreditation and invention discovery;
- Observed laboratory space to evaluate controls against improper use of partner-provided materials;
- Researched publicly-accessible databases regarding patent applications (United States Patent and Trademark Office) and scientific publications (National Institutes of Health/PubMed);
- Reviewed correspondence related to review of publication and presentation requests; and
- Analyzed financial transactions related to partnership agreement projects, including procurement activity, payroll transactions, invoice requests, and sponsor payments.