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October 23, 2018

Dr. Leslie E. Wong, President
San Francisco State University
1600 Holloway Avenue
San Francisco, CA 94132

Dear Dr. Wong:

**Subject: Audit Report 18-73, *Sponsored Programs – Pre-Award Activities*
San Francisco State University**

We have completed an audit of *Sponsored Programs – Pre-Award Activities* as part of our 2018 Audit Plan, and the final report is attached for your reference. The audit was conducted in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*.

I have reviewed the management response and have concluded that it appropriately addresses our recommendations. The management response has been incorporated into the final audit report, which has been posted to Audit and Advisory Services' website. We will follow-up on the implementation of corrective actions outlined in the response and determine whether additional action is required.

Any observations not included in this report were discussed with your staff at the informal exit conference and may be subject to follow-up.

I wish to express my appreciation for the cooperation extended by the campus personnel over the course of this review.

Sincerely,



Larry Mandel
Vice Chancellor and Chief Audit Officer

c: Timothy P. White, Chancellor

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**SPONSORED PROGRAMS – PRE-AWARD
ACTIVITIES**

San Francisco State University

Audit Report 18-73
August 28, 2018

EXECUTIVE SUMMARY

OBJECTIVE

The objectives of the audit were to ascertain the effectiveness of operational and administrative controls related to pre-award certifications and training for sponsored programs and to ensure compliance with relevant governmental regulations, Trustee policy, Office of the Chancellor (CO) directives, and campus and auxiliary organization procedures.

CONCLUSION

We found the control environment for some of the areas reviewed to be in need of improvement.

Based upon the results of the work performed within the scope of the audit, except for the weaknesses described below, the operational and administrative controls for sponsored programs – pre-award activities as of July 20, 2018, taken as a whole, provided reasonable assurance that risks were being managed and objectives were met.

In general, the audit did not reveal any significant internal control problems or weaknesses that would be considered pervasive in their effects on sponsored programs administration. However, the review did identify opportunities for improvement in the areas of conflict-of-interest administration and responsible conduct of research policies and procedures.

Specific observations, recommendations, and management responses are detailed in the remainder of this report.

OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. CONFLICT-OF-INTEREST ADMINISTRATION

OBSERVATION

Administration of conflict-of-interest (COI) statements and related training needed improvement.

We reviewed nine federal awards and ten non-governmental awards, and we found that:

- The campus Financial Conflict of Interest (FCOI) policy and FCOI procedure were outdated and did not always reflect current practices. For example, the definition of a significant financial interest for Public Health Services (PHS)-funded awards had not been updated to reflect revised 2011 regulations, and the requirement for principal investigators (PI) funded by non-governmental awards to file interim COI forms within 30 days of funding renewal was not addressed. In addition, both the policy and procedure stated that PIs with PHS-funded awards were required to attend both in-person and online COI training; however, in practice, only the online training was required.
- In general, the campus did not have a process in place to monitor whether PIs had completed required COI or ethics training for PHS and non-governmental awards. For all five PHS awards and three non-governmental awards we reviewed, PIs did not complete required COI or ethics training.
- COI forms for non-governmental awards were not always timely completed or reviewed. For one award we reviewed, the initial COI form was not completed, and for five additional awards, the COI forms were not timely completed. In addition, for five awards managed by the University Corporation (UCorp), COI forms were not reviewed.

Complete and up-to-date policies and procedures and adequate administration of COI statements and related training decrease the risk of noncompliance with governmental requirements and possible regulatory scrutiny.

RECOMMENDATION

We recommend that the campus:

- a. Update COI policies and procedures to address the issues noted above and communicate the updates to appropriate PIs, pre-award staff, and post-award staff involved in COI certification and training processes.
- b. Implement a documented process to timely identify PIs who are required to complete COI or ethics training, set up PIs in relevant training systems, and monitor completion of training.
- c. Require PIs and key personnel to complete COI or ethics training for the two active PHS-funded awards and the three active non-governmental awards reviewed.

- d. Remind Office of Research and Sponsored Programs (ORSP) pre-award staff that the campus FCOI policy requires COI forms to be completed at the time of proposal submission, and that all initial non-governmental COI forms, including those managed by UCorp, should be reviewed by the designated institutional official.

MANAGEMENT RESPONSE

We concur.

- a. Under the direction of the associate vice president, the ORSP will review and revise its COI policy and procedures to address the issues identified. We will communicate and provide clarity to PIs and ORSP staff the timing of when COI forms and trainings, if required, need to be completed.
- b. ORSP will develop and document our process to monitor and track awards with requirements for PIs to complete COI and ethics trainings. ORSP will designate a compliance specialist to monitor to ensure PIs receive the required training.
- c. ORSP will ask the PIs with active PHS-funded awards to complete COI training and work with San Francisco State human resources to ensure that PIs with non-governmental awards receive ethics training.
- d. The associate vice president, the director, and the compliance officer will have ongoing communications with ORSP staff regarding the requirement that COI forms be completed at the time of proposal submission. We will make changes to our current pre-award and post-award business practices to ensure compliance with this area. ORSP and UCorp will develop and agree on a process for the handling of COI forms when the awards are housed in UCorp and the COI forms need to be timely reviewed and signed by the associate vice president of ORSP.

Anticipated date of completion: February 28, 2019

2. RESPONSIBLE CONDUCT OF RESEARCH

OBSERVATION

The campus policy and procedure related to responsible conduct of research (RCR) did not reflect current practices.

Specifically, the campus RCR policy and procedure stated that RCR training certification for students and trainees engaged in research on applicable grants must be signed by the PI and submitted to the ORSP before these individuals can be hired or receive any payments. However, the campus practice was to allow RCR training to be completed within a reasonable time frame and did not require proof of RCR training before hiring or payment processing.

Keeping policies and procedures current decreases the risk of noncompliance with governmental requirements and increases accountability.

RECOMMENDATION

We recommend that the campus update RCR policies and procedures to reflect current practices relating to the timing of RCR training completion and communicate these updated policies and procedures to key ORSP personnel involved in administering RCR requirements.

MANAGEMENT RESPONSE

We concur.

The ORSP will revise its RCR policy and procedures to reflect our current RCR training completion practices. The revised policy and procedures will be communicated to all ORSP staff.

Anticipated date of completion: February 28, 2019

GENERAL INFORMATION

BACKGROUND

Sponsored programs include all work performed under grants or contracts funded by external sources, such as federal agencies, state agencies, and non-profit organizations. Sponsored programs generally involve research, training, outreach, and other scholarly activities that contribute to the mission of the university.

As a condition of accepting sponsor funds, campuses must comply with a variety of award terms and conditions, as well as applicable state and federal regulations. Each campus may have one or several offices that provide oversight to ensure that sponsored program activities are conducted in compliance with relevant requirements.

In order to ensure the highest standards of research integrity, certification and training programs are essential. Major areas covered by these programs include:

- **Conflicts of interest:** Disclosing and managing situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a researcher's professional judgment in conducting or reporting research. The National Institutes of Health (NIH), National Science Foundation (NSF), and state of California all have specific conflict-of-interest reporting and training requirements.
- **Responsible conduct of research (RCR):** Ensuring the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. NIH, NSF, and the National Institute of Food and Agriculture (NIFA) have specific requirements for RCR training.
- **Human subjects:** Protecting the rights and ensuring the safety of human subjects participating in research projects. The Department of Health and Human Services requires that a federal-wide assurance with its Office for Human Research Protections be obtained. Additionally, NIH requires education on the protection of human research participants.
- **Animal subjects:** Protecting animal welfare and ensuring the humane care and use of live animals in research projects. The Animal Welfare Act (AWA) requires that training be provided to personnel involved in the care and treatment of certain research animals. Along with the AWA, the United States PHS requires facilities using live vertebrate animals in research to adhere to additional requirements, including the provision of a written animal welfare assurance of compliance.
- **Suspension and debarment:** Ensuring that employees who have been suspended, debarred, or charged with criminal activity are not allowed to administer federal funds on behalf of the university.

Within the California State University (CSU) system, the CO's Office of Research Initiatives and Partnerships contributes systemwide support and promotion for CSU research, scholarship, and creative activities. In addition, the CO Sponsored Programs Administration department provides systemwide support related to the administration of research and sponsored

programs, including developing systemwide policies, providing training, analyzing legislation, and providing general guidance to campuses and auxiliaries engaged in externally funded projects. A number of systemwide collaborative groups have been formed to support sponsored programs within the CSU, including the Council of Chief Resource Officers and the Research Administration Committee. Systemwide policies for sponsored programs administration are primarily contained within Integrated California State University Administrative Manual (ICSUAM) §11000, et seq.

At San Francisco State University (SFSU), ORSP provides pre-award support services for developing and submitting external grant proposals for all sponsored projects. ORSP is also generally responsible for the administration of sponsored projects after an award is accepted, except for certain non-governmental sponsored projects where the funder requires the recipient to have 501(c)(3) status; these projects are administered by UCorp after award acceptance.

ORSP's pre-award responsibilities include ensuring COI forms are timely completed and reviewed; tracking and monitoring required training related to COI, RCR, and human and animal protection; and performing suspension and debarment reviews for employees and vendors. In addition, the ORSP human and animal protections unit supports the campus institutional review board that reviews all proposed research involving human subjects and the institutional animal care and use committee that reviews and provides oversight for research involving animal subjects.

SCOPE

We visited the SFSU campus from July 9, 2018, through July 20, 2018. Our audit and evaluation included the audit tests we considered necessary in determining whether operational and administrative controls are in place and operative. The audit focused on procedures in effect from July 1, 2015, through July 20, 2018.

Specifically, we reviewed and tested:

- Adherence to conflict-of-interest disclosure and training requirements.
- Maintenance of assurances for human and animal research.
- Compliance with human subject, animal welfare, and responsible conduct of research training requirements.
- Maintenance of certifications relating to suspension and debarment for PIs and other key personnel involved in federal sponsored projects.

As a result of changing conditions and the degree of compliance with procedures, the effectiveness of controls changes over time. Specific limitations that may hinder the effectiveness of an otherwise adequate system of controls include, but are not limited to, resource constraints, faulty judgments, unintentional errors, circumvention by collusion, and management overrides. Establishing controls that would prevent all these limitations would not be cost-effective; moreover, an audit may not always detect these limitations.

Our testing and methodology, which was designed to provide a review of key operational and administrative controls, included interviews, walkthroughs, and detailed testing on certain sponsored programs certification and training requirements. Our review did not include all aspects of pre-award activities, such as proposal development and approval, institutional review boards and institutional animal care and use committees, or compliance with specific institutional protocols.

CRITERIA

Our audit was based upon standards as set forth in federal and state regulations and guidance; CSU Board of Trustee policies; CO policies, letters, and directives; campus procedures; and other sound administrative practices. This audit was conducted in conformance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing*.

This review emphasized, but was not limited to, compliance with:

- Code of Federal Regulations Title 2, Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*
- Code of Federal Regulations Title 42, Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*
- America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act, Section 7009
- Animal Welfare Act, Section 2.32
- Health Research Extension Act of 1985, Public Law 99-158, *Animals in Research*
- PHS *Policy on Humane Care and Use of Laboratory Animals*
- NIH *Grants Policy Statement*
- NIH Notice OD-00-039, *Required Education in the Protection of Human Research Participants*
- NIH Notice OD-10-019, *Update on the Requirement for Instruction in the Responsible Conduct of Research*
- NSF *Proposal and Award Policies and Procedures Guide*
- NIFA Research Terms and Conditions, Article 7
- ICSUAM §11010.02, *Financial Conflict of Interest*
- Coded memorandum Human Resources (HR) 2015-03, *Ethics Regulations and COI Code Training*
- HR 2015-05, *Principal Investigators – Nongovernmental*
- SFSU *Financial Conflict of Interest Policy*
- SFSU *Financial Conflict of Interest Procedure*
- SFSU *Responsible Conduct of Research Policy*
- SFSU *Responsible Conduct of Research Procedure*

AUDIT TEAM

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