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September 17, 2019

Dr. Adela de la Torre, President
San Diego State University
5500 Campanile Drive
San Diego, CA 92182

Dear Dr. de la Torre:

Subject: Audit Report 19-69, Sponsored Programs – Pre-Award Activities, San Diego State University

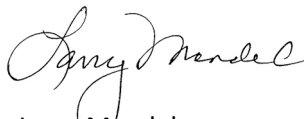
We have completed an audit of *Sponsored Programs – Pre-Award Activities* as part of our 2019 Audit Plan, and the final report is attached for your reference. The audit was conducted in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal 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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The California State University
Audit and Advisory Services

**SPONSORED PROGRAMS –
PRE-AWARD ACTIVITIES**

San Diego State University

Audit Report 19-69
August 16, 2019

EXECUTIVE SUMMARY

OBJECTIVE

The objectives of the audit were to ascertain the effectiveness of operational and administrative controls related to pre-award activities 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

Based upon the results of the work performed within the scope of the audit, the operational and administrative controls for sponsored programs – pre-award activities as of July 18, 2019, taken as a whole, provided reasonable assurance that risks were being managed and objectives were met. However, the review did identify opportunities for improvement in conflict-of-interest administration.

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

OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. CONFLICT OF INTEREST

OBSERVATION

Conflict-of-interest (COI) administration for sponsored programs needed improvement.

We reviewed campus COI policies and procedures, as well as COI documentation for 14 sponsored projects, and found that:

- The campus *Financial COI Policy for Investigators with Private Institution/Non-Governmental Funding* did not fully address ethics training requirements for non-governmental awards. For four of the five non-governmental awards we reviewed, principal investigators (PI) were not assigned ethics training, and for one award, ethics training was not completed timely.
- In general, the campus did not document reviews of COI disclosure forms for non-governmental awards. Two COI disclosure forms had positive responses, and although a management plan was not necessary in either case, the campus could not provide documentation of the review or the determination that further action was not necessary.
- PIs or key personnel on projects funded by Public Health Services (PHS) did not always complete COI training or complete the training timely. For two PHS-funded projects, the required training was not completed, and for one project, the training was not completed timely.

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 ethics training requirements for non-governmental awards, and communicate these updates to PIs and relevant staff members.
- b. Implement a documented process to timely identify PIs who are required to complete ethics and COI training and to monitor completion of such training.
- c. Implement a documented process to review COI forms and document follow-up actions as needed.
- d. Require PIs and key personnel to complete COI or ethics training for the PHS-funded award and the three active non-governmental awards noted above.

MANAGEMENT RESPONSE

We concur.

- a. The campus has updated COI policies and procedures to address ethics training requirements for non-governmental awards. Updates have been communicated to PIs and relevant staff members.
- b. The campus has implemented a documented process to timely identify PIs who are required to complete ethics and COI training and to monitor completion of such training.
- c. The campus has implemented a documented process to review COI forms and document follow-up actions as needed.
- d. The campus has notified the PIs and key personnel of the training requirement and, per CSU policy, they will have six months to complete training.

Tentative completion date: February 16, 2020

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 Public Health Service (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 Diego State University (SDSU), the Division of Research Affairs (DRA) and the San Diego State University Research Foundation (Research Foundation) share responsibility for pre-award activities for sponsored programs. DRA's pre-award responsibilities include ensuring that COI forms are timely completed and reviewed; and tracking and monitoring required training related to COI, RCR, and human and animal protection. The Research Foundation provides support services for developing and submitting external grant proposals, as well as approvals related to indirect cost rate for all sponsored projects, and performing suspension and debarment reviews for employees and vendors. In addition, under DRA, the institutional review board reviews all proposed research involving human subjects and the institutional animal care and use committee reviews and provides oversight for research involving animal subjects.

SCOPE

We visited SDSU from June 24, 2019, through July 18, 2019. 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 January 1, 2017, through July 18, 2019.

Specifically, we reviewed and tested:

- Administration of the proposal and indirect-cost rate approval process.
- 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.
- Suspension and debarment review processes for principal investigators 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 budgeting; 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 (CFR) Title 2, Part 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*
- CFR 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 §11002.03, *Pre-Award Proposal Review and Approval*
- ICSUAM §11010.02, *Financial Conflict of Interest*
- Human Resources (HR) Coded Memorandum 2015-05, *Principal Investigators - Nongovernmental*
- HR Coded Memorandum 2018-02, *Ethics Regulations and COI Code Training*
- CSU *PI Quick Reference Guide*
- SDSU *COI Policy for Investigators with Private Institution/Non-Governmental Funding*

AUDIT TEAM

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Senior Auditor: Christina Chen