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August 17, 2018

Dr. Karen S. Haynes, President
California State University San Marcos
333 S. Twin Oaks Valley Road
San Marcos, CA 92096

Dear Dr. Haynes:

**Subject: Audit Report 18-72, *Sponsored Programs – Pre Award Activities*,
California State University San Marcos**

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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The California State University
Audit and Advisory Services

SPONSORED PROGRAMS – PRE-AWARD ACTIVITIES

**California State University
San Marcos**

Audit Report 18-72
July 19, 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 June 22, 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 some areas, such as conflict-of-interest administration, policies and procedures relating to the responsible conduct of research (RCR), and monitoring for training for projects involving human-subject research.

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

OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. CONFLICT-OF-INTEREST ADMINISTRATION

OBSERVATION

The campus and California State University San Marcos University Corporation (Corporation) administration of conflict-of-interest statements and related training needed improvement.

We found that:

- Neither the campus nor the Corporation had a conflict-of-interest policy that addressed California State University conflict-of-interest and ethics training requirements for non-government projects. In our review, we found that the campus did not use California Fair Political Practices Commission (FPPC) Form 700-U, *Statement of Economic Interests for Principal Investigators* for non-government conflict-of-interest filings. In addition, we reviewed six non-governmental projects and found that for four projects, principal investigators (PIs) either did not complete ethics training or did not complete the training timely.
- The Corporation's conflict-of-interest policy did not reflect current practices. Specifically, the policy stated that conflict-of-interest training should be completed every four years for projects funded by the National Science Foundation (NSF); however, this was not required by the sponsor and did not reflect current practices. In addition, the policy stated that all disclosure forms would be reviewed initially by the Corporation's director of sponsored projects; however, the forms were reviewed by the sponsored projects administrator or the grants and contract analyst.
- In general, the Corporation did not have a tracking process in place to monitor whether PIs had completed renewal conflict-of-interest forms timely. We reviewed eight awards funded by the NSF or the National Institutes of Health (NIH), and we found that three renewal forms could not be located.

Adequate administration of conflict-of-interest statements and related training decreases the risk of noncompliance with governmental requirements and possible regulatory scrutiny.

RECOMMENDATION

We recommend that the campus, in conjunction with the Corporation:

- a. Update conflict-of-interest 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 conflict-of-interest certification and training processes.
- b. Implement the use of Form 700-U for non-government funded projects.
- c. Implement a documented process to obtain and track renewal conflict-of-interest forms from PIs.

MANAGEMENT RESPONSE

We concur. The campus will update conflict-of-interest 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 conflict-of-interest certification and training processes, implement the use of Form 700-U for non-government funded projects, and implement a documented process to obtain and track renewal conflict-of-interest forms from PIs.

Estimated completion date: January 18, 2019

2. RESPONSIBLE CONDUCT OF RESEARCH

OBSERVATION

Campus administration of RCR requirements needed improvement.

We found that the campus Institutional Plan for Training on Responsible Conduct of Research (the Plan) had not been updated to reference or incorporate all federal requirements, or to reflect current campus practices.

Specifically, we found that:

- The Plan did not address the frequency of required training or RCR requirements for research funded by the United States Department of Agriculture (USDA).
- The Plan stated that the office of sponsored projects would retain copies of RCR training certifications; however, in practice, PIs were responsible for maintaining training records for their projects.

In addition, we noted that in general, the campus did not have a central tracking or verification process in place to monitor whether RCR training had been completed by student trainees. We reviewed 10 trainees from five federally sponsored projects that required RCR training, and we found that in five instances, the campus could not provide evidence that trainees had completed the training. In an additional four instances, the PI used an alternative RCR training plan but did not obtain documented approval for the alternative plan from the dean of the office of graduate studies and research.

Appropriate oversight and administration of RCR training helps to ensure that PIs and students follow established policies and procedures and reduces the campus exposure to risk related to noncompliance with federal regulations.

RECOMMENDATION

We recommend that the campus:

- a. Update the Plan to address the issues noted above.
- b. Establish a documented process to monitor RCR training completion.

- c. Remind PIs of their responsibility to provide RCR training to student trainees, obtain prior approval for alternative training plans, and maintain records of training completion.

MANAGEMENT RESPONSE

We concur. The campus will update the Plan to address the issues noted above, establish a documented process to monitor RCR training completion and remind PIs of their responsibility to provide RCR training to student trainees, obtain prior approval for alternative training plans, and maintain records of training completion.

Estimated completion date: January 18, 2019

3. HUMAN-SUBJECT PROTECTION TRAINING

OBSERVATION

PIs who conducted human-subject research did not always complete required training.

Campus policies and procedures require all researchers, including faculty, students, and staff conducting human-subject research, to complete online human-subject protection training. This training must remain current throughout the human-subject research.

We reviewed 10 awards involving human-subject research and found that:

- In two instances, the PI did not complete the required training. In another instance, the PI's training was expired at the time of the institutional review board.
- In one instance, the PI's training expired during the period of human-subject research.

Effective administration of human-subject protection training helps to ensure compliance with federal regulations and sponsor requirements and reduces the risks and potential liability to the campus.

RECOMMENDATION

We recommend that the campus:

- a. Develop a process to monitor human-subject protection training for all PIs who conduct human-subject research and ensure that the training remains current throughout the research.
- b. Require the PIs noted above to complete human-subject protection training for any awards that are currently active.

MANAGEMENT RESPONSE

We concur. The campus will develop a process to monitor human-subject protection training for all PIs who conduct human-subject research and ensure that the training remains current

throughout the research and require the PIs noted above to complete human-subject protection training for any awards that are currently active.

Estimated completion date: January 18, 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 NIH, NSF, and state of California all have specific conflict-of-interest reporting and training requirements.
- **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 California State University San Marcos (CSUSM), under the office of graduate studies and research, the campus pre-award grants office provides support services for developing and submitting external grant proposals, including ensuring initial COI forms are completed and reviewed timely. The Corporation office of sponsored projects is responsible for the administration of sponsored programs after an award is accepted, including obtaining and reviewing renewal COI forms. In addition, the campus has an institutional review board that reviews all proposed research involving human subjects and an institutional animal care and use committee that reviews and provides oversight for research involving animal subjects. In fiscal year 2016/17, CSUSM had \$11.1 million in expenditures for federally sponsored programs.

SCOPE

We visited the San Marcos campus from June 11, 2018, through June 22, 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 June 22, 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 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 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*
- CSUSM *Corporation Conflict-of-Interest Policy*
- CSUSM *Institutional Plan for Training on Responsible Conduct of Research*
- CSUSM *Policy on Human Subject Protection in Research*

AUDIT TEAM

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