

Audit and Advisory Services
401 Golden Shore
Long Beach, CA 90802-4210

November 16, 2021

Dr. Lynnette Zelezny, President
California State University, Bakersfield
9001 Stockdale Highway
Bakersfield, CA 93311

Dear Dr. Zelezny:

**Subject: Audit Report 21-16, *Sponsored Programs Pre-Award Activities*,
California State University, Bakersfield**

We have completed an audit of *Sponsored Programs Pre-Award Activities* as part of our 2021-2022 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 will be 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,



Vlad Marinescu
Vice Chancellor and Chief Audit Officer

c: Joseph I. Castro, Chancellor
Adam Day, Chair, Committee on Audit
Jane W. Carney, Vice Chair, Committee on Audit

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SPONSORED PROGRAMS PRE-AWARD ACTIVITIES

**California State University,
Bakersfield**

Audit Report 21-16
November 16, 2021

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, except for the weaknesses described below, the operational and administrative controls for sponsored program pre-award activities as of August 23, 2021, taken as a whole, provided reasonable assurance that risks were being managed and objectives were met.

In general, we noted that the campus had an appropriate framework for the administration of sponsored program pre-award activities; however, we identified a few areas needing improvement. We found that the campus did not have written policies and procedures to determine whether key personnel assigned to an award had been suspended or debarred before the award was accepted, and the administration of sponsored programs' export controls. Also, the administration and timeliness of principal investigators' (PI) completion of conflict-of-interest (COI) statements and related training needed improvement. Specifically, certain policies and procedures had not been established or did not reflect current processes, and the campus did not have a delegation of authority for the provost and vice president of academic affairs to review and approve sponsored program proposal submissions on behalf of the campus president.

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

OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. SUSPENSION AND DEBARMENT

OBSERVATION

The campus did not have written policies and procedures to determine whether key personnel assigned to an award had been suspended or debarred before the award was accepted.

In addition, the campus did not have an established process during the proposal submission stage to verify that key personnel assigned to an award, such as PIs, had not been suspended or debarred. For example, sponsored program projects funded by the National Institutes of Health require this verification, which can be fulfilled via self-disclosure from the PI on the COI section of the proposal questionnaire or through a restricted party screening service such as Visual Compliance.

Written policies and procedures and established processes for determining whether key personnel have been suspended or debarred before award acceptance can help decrease the risk of noncompliance with governmental and/or sponsor requirements and ensure proper oversight over sponsored programs.

RECOMMENDATION

We recommend that the campus:

- a. Establish written policies and procedures to determine whether key personnel assigned to an award have been suspended or debarred before the award acceptance.
- b. Implement a process during the proposal submission stage to verify that key personnel, such as PIs, assigned to sponsored program projects have not been suspended or debarred.
- c. Communicate these policies, procedures, and processes to PIs and relevant campus administrators and staff.

MANAGEMENT RESPONSE

The grants, research and sponsored programs (GRaSP) pre-award office will update its suspension and debarment policies and procedures to address areas of concern. Recently, the GRaSP pre-award office updated the proposal routing forms for key personnel to attest to suspension and debarment requirements. The GRaSP pre-award office verifies key personnel for suspension and debarment via the Descartes Visual Compliance platform and uploads the documentation into the proposal routing package.

The GRaSP pre-award office will document and communicate these procedures in the *Pre-Award Program Administration Guide* to the campus community by January 31, 2022.

2. EXPORT CONTROLS

OBSERVATION

The campus did not have written policies and procedures or established processes for the general administration of sponsored programs export controls.

We found that for sponsored program export controls, the campus did not have clearly defined roles and responsibilities, procedures for identifying projects with potential export control considerations or restrictions, procedures for applying fundamental research exclusion, or training requirements.

In addition, we found that the campus proposal questionnaire included an export control section to be completed by the PI, in which the PI was expected to confirm whether or not a project would involve export control activities. However, the campus did not maintain documentation showing that PIs were provided training defining sponsored program export control requirements or subsequent steps a PI must perform when export control requirements were applicable to the project.

Written policies and procedures and an established process for the administration of sponsored programs export controls can help to decrease the risk of noncompliance with governmental and/or sponsor requirements and ensure proper oversight over sponsored programs.

RECOMMENDATION

We recommend that the campus:

- a. Establish written policies and procedures and implement corresponding processes for the administration of sponsored program export controls that address the issues noted above.
- b. Communicate these policies, procedures, and processes to PIs and relevant campus administrators and staff.

MANAGEMENT RESPONSE

Export controls are a university-wide function and responsibility. Over the next six months, the GRaSP pre-award office will coordinate with the office of the provost, sponsored programs post-award, and the office of risk management to develop and implement policies and procedures regarding export controls on the campus. These offices will work together to define export controls, associated training requirements, and roles or responsibilities of the various campus offices based on the committee's recommendations.

Currently, GRaSP pre-award's key personnel are required to identify export control concerns in the proposal routing package at the time of submission for sponsored programs.

The GRASP pre-award office will provide access to an export controls training module through the CITI platform, which will be shared and made available university-wide by May 31, 2022.

The revised procedures will be updated in the *Pre-Award Program Administration Guide* and communicated to the campus by April 19, 2022.

3. CONFLICT OF INTEREST

OBSERVATION

Administration of COI-related training and COI statements needed improvement.

We reviewed the records of 21 PIs working on federal and non-governmental projects and found that:

- In three instances, the PI did not complete COI-related ethics training within six months of receiving the grant or contract, as required by the campus *Sponsored Program Post Award Administration* policy. We noted that pre-award staff in the grants, research, and sponsored programs (GRASP) office were responsible for proposal development, award and contract negotiations, and some training, while post-award staff were responsible for accounting and certain compliance elements. There was some overlap in staff responsibilities in these offices related to training, particularly when an award transferred from the pre-award to the post-award phase. However, we found that each office had a different understanding of the six-month training requirement, and the campus did not clearly define which office was responsible for ensuring that PIs completed required ethics training within the required time frame.
- In one instance, the PI completed the incorrect COI statement during proposal submission, and in another, the PI did not complete an updated COI statement after a federal project renewed.

Proper administration of COI-related training and COI statements can help to decrease the risk of noncompliance with governmental and/or sponsor-specific requirements and ensure proper oversight over sponsored programs.

RECOMMENDATION

We recommend that the campus:

- a. Update policies and procedures to clearly define which office is responsible for ensuring that PIs timely complete required COI-related training.
- b. Ensure that PIs complete the correct COI statements before and after award acceptance.
- c. Communicate the revised policies and procedures and reiterate to PIs and relevant campus administrators and staff the importance of timely completion of training and the proper COI statements before and after award acceptance.

MANAGEMENT RESPONSE

Completion of COI training is addressed through the CSU Learn and CITI platforms for non-federal and federal awards, respectively. The GRaSP pre-award office will update its COI policies and procedures to address areas of concern regarding the timely completion of required COI-related training. The office will also communicate to key personnel the requirement to complete the appropriate COI form, requiring timely completion of the form in the proposal routing package and before award acceptance. The GRaSP pre-award office will re-verify COI forms before submitting awards to the post-award office.

The GRASP pre-award office will document and communicate these procedures in the *Pre-Award Program Administration Guide* to the campus by January 31, 2022.

4. POLICIES AND PROCEDURES**OBSERVATION**

Campus policies and procedures related to responsible conduct of research (RCR) and human and animal research were not current or did not reflect current processes.

We found that:

- The campus did not have current written policies and procedures for RCR, including clearly defined roles and responsibilities and training requirements. Instead, the campus had a draft policy dated April 2018.
- The campus *Institutional Review Board for Human Subjects Research* policy was last updated in July 2009 and still referenced a superseded federal requirement.
- The campus *Policy and Procedures for the Protection of Animals in Research and Education* policy was last updated in November 1997 and still referenced a superseded sponsor requirement. Also, at least one section of this policy did not reflect current processes.

Current policies and procedures can help to decrease the risk of noncompliance with governmental requirements and improve the effectiveness and consistency of operations.

RECOMMENDATION

We recommend that the campus:

- a. Establish RCR policies and procedures and update the human and animal research policies and procedures to reflect current processes.
- b. Communicate and distribute new and updated policies and procedures to PIs and relevant campus administrators and staff.

MANAGEMENT RESPONSE

For RCR, the GRaSP pre-award office adheres to the CSU policy regarding RCR training. The GRaSP pre-award office will develop, document, and communicate university procedures to PIs and the campus community by November 30, 2021.

For the Institutional Animal Care and Use Committee (IACUC), the GRaSP pre-award research compliance analyst, the university research ethics review coordinator, and IACUC members will update policies and procedures and communicate them to PIs and the campus community by January 31, 2022.

For the Institutional Review Board (IRB), the GRaSP pre-award research compliance analyst, the university research ethics review coordinator, and IRB members will provide the draft version of updated policies and procedures to the academic senate for review and approval by April 19, 2022.

5. DELEGATION OF AUTHORITY

OBSERVATION

The campus did not have a written delegation of authority for the provost and vice president of academic affairs to review and approve sponsored program proposal submissions on behalf of the campus president.

Per Integrated California State University Administrative Manual (ICSUAM) §11002.03, *Sponsored Programs Pre-Award Proposal Review and Approval*, proposals for sponsored programs shall not be submitted to the sponsor without prior approval from the university president or the president’s designee for the technical proposal and support of the university mission.

A documented delegation of authority helps to ensure that appropriate individuals review and approve sponsored program proposal submissions and decreases the risk of noncompliance with California State University (CSU) requirements.

RECOMMENDATION

We recommend that the campus establish a written delegation of authority for the provost and vice president of academic affairs to review and approve sponsored program proposal submissions on behalf of the campus president.

MANAGEMENT RESPONSE

The campus will provide a written delegation of authority for the provost and vice president of academic affairs to review and approve sponsored program proposal submissions on behalf of the campus president by November 30, 2021.

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:

- COI: 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 COI 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 researchers to obtain a federal-wide assurance with its Office for Human Research Protections. 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.
- Export controls: Ensuring that projects subject to export control requirements are properly identified. The Department of Commerce, the State Department, and the Department of the Treasury Office of Foreign Assets Control have specific requirements.

Within the 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 ICSUAM §11000, et seq.

At California State University, Bakersfield (CSUB), the GRASP office in the Division of Academic Affairs is responsible for pre-award activities for sponsored programs. The GRASP office assists faculty and staff seeking external funding and other resources to support research and service projects for students, faculty, and the CSUB community. Specific services include funding searches, proposal development, outreach and reporting, and award and contract negotiations. The GRASP office also provides support for, among others, the Research Council of the University, Student Research Scholars Program, Student Research Competition, and Travel Support for Student Researchers. In addition, GRASP assists the Institutional Review Board and provides ethics training for proposed research involving human and animal subjects.

SCOPE

Due to temporary operating procedures and limitations resulting from the COVID-19 public health emergency, we performed fieldwork remotely from July 19, 2021, through August 23, 2021. 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, 2019, to August 23, 2021.

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.
- Compliance with export control regulations, application of the fundamental research exemption, and administration of controlled research 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 aspects of the pre-award activities. Our review was limited to gaining reasonable assurance that essential elements of the sponsored programs pre-award operation were in place and did not examine all aspects of the program.

CRITERIA

Our audit was based upon standards as set forth in federal and state regulations and guidance; Trustee policy; Office of the Chancellor directives; and campus procedures; as well as sound administrative practices and consideration of the potential impact of significant risks. 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
- AWA 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
- U.S. Department of Commerce *Export Administration Regulations*
- U.S. State Department *International Traffic in Arms*
- U.S. Department of the Treasury Office of Foreign Assets Control Sanctions Programs
- 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 2018-02, *Ethics Regulations and COI Code Training*
- CSU *Export Controls Manual*
- CSU *PI Quick Reference Guide*

- CSUB and Auxiliary for Sponsored Programs Administration, *Pre-Award Program Administration Guide*
- CSUB *Policy, Procedures and Practices: CSUB Institutional Review Board for Human Subject Research*
- CSUB *Policy and Procedures for the Protection of Animals in Research and Education*
- CSUB *Sponsored Program Post Award Administration*

AUDIT TEAM

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