

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SAINT LOUIS UNIVERSITY'S
MANAGEMENT OF NIH GRANT
AWARDS DID NOT COMPLY WITH ALL
FEDERAL REQUIREMENTS BUT
COMPLIED WITH FINANCIAL
CONFLICT OF INTEREST
REQUIREMENTS**

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: June 2023

Report No. A-07-20-05127

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Extramural research awards accounted for more than 84 percent of the \$45 billion that the National Institutes of Health (NIH) received in funding for Federal fiscal year 2022. Prior OIG work highlighted an increased need for transparency in research funding and identified several areas in which NIH could improve how it oversees the grants that it awards each year. This audit of Saint Louis University (the University) is part of a series of audits of institutions of higher education.

Our objectives were to determine whether the University: (1) managed NIH awards in accordance with Federal and award requirements and (2) had policies and procedures in place that were designed to meet Financial Conflict of Interest (FCOI) requirements for training and monitoring.

How OIG Did This Audit

Our audit covered costs totaling almost \$67 million associated with 795 NIH awards (managed in 500 award fund accounts) that the University received between January 1, 2017, and December 31, 2019.

We reviewed the University's policies and procedures to determine whether the University had controls in place, and we judgmentally selected 5 of the University's 500 award fund accounts, from which we judgmentally selected and reviewed 31 costs totaling \$426,443 that the University charged to the awards.

Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements but Complied With Financial Conflict of Interest Requirements

What OIG Found

The University did not always manage NIH awards in accordance with Federal and award requirements. Specifically, of the 31 judgmentally selected costs totaling \$426,443 that we reviewed, we determined that 6 costs totaling \$42,578 did not comply with Federal and award requirements for allowability of costs. These errors occurred because the controls that the University had in place, to include policies and procedures, were inadequate to ensure that the University always managed its NIH awards in accordance with Federal and award requirements. For our second objective, we determined that the University had policies and procedures in place that were designed to meet FCOI requirements for training and monitoring of outside interest disclosures.

We also determined that the University's controls, including policies and procedures, were not always sufficient to ensure that it properly monitored subawards to identify possible investigator misconduct that may have impacted the conduct or performance of another NIH award. Of the 31 judgmentally selected costs we reviewed, 1 subrecipient cost was associated with possible subrecipient investigator misconduct in an unrelated NIH award not associated with the University.

What OIG Recommends and Saint Louis University Comments

We recommend that the University: (1) refund \$263 to NIH for unallowable travel costs; (2) ensure that it always manages NIH awards in accordance with Federal and award requirements, by strengthening procedures and controls; (3) enhance its existing controls by developing and implementing policies and procedures to ensure that either the internal audits conducted by its internal audit firm, the University's compliance department, or both, review costs that the University claims for its NIH awards; and (4) strengthen its controls, to include policies and procedures, to ensure that it properly monitors its subaward subrecipients.

The University concurred with all of our recommendations and described corrective actions it had taken or planned to take. Specifically, the University stated that it had refunded to NIH the full amount of the unallowable travel expenditure and that it had implemented a new automated financial system, a restructuring of its grants accounting function, the updating of policy, and plans to provide additional training to staff.

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INTRODUCTION

WHY WE DID THIS AUDIT

Extramural research awards accounted for more than 84 percent of the \$45 billion that the National Institutes of Health (NIH) received in funding for Federal fiscal year (FY) 2022.¹ The Office of Inspector General's (OIG) oversight has examined NIH's efforts to ensure the integrity and the effective management of its grant application and selection processes, and has reviewed NIH-funded research institutions' compliance with Federal requirements and NIH policies that establish controls for NIH grants, contracts, and other transactions. Prior OIG work highlighted an increased need for transparency in research funding and identified several areas in which NIH could improve how it oversees the billions of dollars in grants for research that it awards each year. More specifically, OIG previously identified NIH's oversight of grants to foreign applicants as a risk to the Department of Health and Human Services (HHS) in terms of meeting program goals and the appropriate use of Federal funds.² We found in a recent audit that of the 1,875 institutions that received NIH funding in FY 2018 and were required to have publicly available Financial Conflict of Interest (FCOI) policies, 1,013 institutions did not have FCOI policies posted on their websites.³ Additionally, an OIG study found that two-thirds of grantees failed to meet one or more requirements for investigators' disclosure of all foreign financial interest and support.⁴ We conducted an audit at Saint Louis University (the University), as part of a series of audits of institutions of higher education, as a result of findings within one of the University's prior Single Audits related to its Federal awards.⁵

¹ Extramural research is supported by NIH and conducted by investigators in universities, academic health centers, and independent research institutes.

² Testimony of Gary L. Cantrell, Deputy Inspector General for Investigations, Office of Investigations, before the Senate Committee on Health, Education, Labor and Pensions, April 22, 2021, available at https://oig.hhs.gov/documents/testimony/316/Gary_Cantrell_Testimony_Senate_HELP_Foreign_Influence.pdf. See also [*The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*](#) (A-05-21-00025), Jan. 25, 2023.

³ [*The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place For Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations*](#) (A-03-19-03003), Sep. 25, 2019.

⁴ [*Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interest and Other Support*](#) (OEI-03-20-00210), Jun. 2, 2022.

⁵ Under the provisions of 45 CFR § 75.501(a), a non-Federal entity that expends \$750,000 or more in Federal awards during an FY must be the subject of a Single Audit or program-specific audit of those awards.

OBJECTIVES

Our objectives were to determine whether the University: (1) managed NIH awards in accordance with Federal and award requirements and (2) had policies and procedures in place that were designed to meet FCOI requirements for training and monitoring.

BACKGROUND

NIH Award Funding

NIH is the largest source of public funding for medical research in the world. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability.

Institutions of higher education may apply for NIH awards to fund research that is conducted by investigators.⁶ These investigators may use the awards to support a variety of needs, including staffing laboratories, purchasing supplies and equipment, and attending national and international conferences to discuss research findings. For research conducted by investigators, institutions of higher education charge to awards the costs that are necessary and reasonable, allocable, and adequately documented.

To further address their research needs, some investigators may also seek research support from other organizations, including foreign entities. The universities, medical schools, and other research institutions that receive NIH awards are responsible for soliciting and reviewing investigators' significant financial interests, determining whether those significant financial interests constitute FCOIs, and then managing any FCOIs and reporting them to NIH.⁷

The institution must report financial conflicts of interest to NIH through the submission of an initial and annual report.⁸

⁶ Investigators include project directors, principal investigators, and any other individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of research either funded or proposed for such funding by the Public Health Service (PHS), which includes NIH. 42 CFR § 50.603.

⁷ Institutions also must report "other support" to NIH as part of the Just-in-Time procedures when the application is under consideration for funding. *NIH Grants Policy Statement*, section 2.5.1. This report did not review the Just-in-Time reporting process.

⁸ 42 CFR § 50.605(b) and *NIH Grants Policy Statement*, section 4.1.10. An institution must submit these annual reports to NIH each year within a competitive segment or until the institution reports that the FCOI no longer exists.

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

Federal regulations at 45 CFR part 75 provide uniform administrative requirements, cost principles, and audit requirements for Federal awards to non-Federal entities such as awards made by NIH to institutions of higher education.

NIH Grants Policy Statement

The *NIH Grants Policy Statement* is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH awards. Accordingly, the *NIH Grants Policy Statement* is the primary source of policy guidance that NIH uses to administer awards.⁹

Financial Conflict of Interest Regulations

In 2011, HHS published a final rule requiring that each institution that applies for or receives research funding from NIH make its FCOI policy available on a publicly accessible website.¹⁰ This final rule built upon a 1995 regulation requiring each institution to maintain an up-to-date, written, enforced FCOI policy.¹¹ The 2011 FCOI regulations apply to institutions that apply for or seek NIH funding for research.

The requirement to post FCOI policies on a publicly accessible website was part of an HHS effort to update the standards for ensuring that there is a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from investigator FCOIs.¹² In that spirit, the resulting 2011 FCOI regulations were designed to increase accountability, add transparency, enhance regulatory compliance, promote effective institutional management of FCOIs, and strengthen compliance oversight.¹³ NIH is responsible for overseeing institutional compliance with the 2011 FCOI regulations for NIH-funded awards.¹⁴

⁹ NIH published four different versions of the *NIH Grants Policy Statement* that are applicable during our audit period, in November 2016, October 2017, October 2018, and December 2019; however, the language relevant to our findings did not change from one version to the next.

¹⁰ 42 CFR § 50.604(a).

¹¹ 76 Fed. Reg. 53256, 53267 (Aug. 25, 2011).

¹² 42 CFR § 50.601.

¹³ NIH, "Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR part 50, subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations)" (Oct. 22, 2015). Available online at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm> (accessed on Mar. 2, 2023).

¹⁴ 76 Fed. Reg. 53256 (Aug. 25, 2011).

NIH Financial Conflict of Interest Reporting

An FCOI exists when an institution reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.¹⁵ An investigator's financial interests may result in a significant financial interest.

For its part, NIH is not required to ensure proactively that investigators disclose all sources of financial interests. Instead, it provides oversight of institutions' compliance with the relevant regulations, policies, and procedures. On its policy and compliance webpage, NIH noted that:¹⁶

The NIH is committed to preserving the public's trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.

Institutions are responsible for soliciting and reviewing disclosures of significant financial interests from each investigator who is planning to participate in or is participating in NIH-funded research.¹⁷ Institutions are also responsible for reporting to NIH any significant financial interests that constitute an FCOI and that have not been eliminated.¹⁸

Investigators are required to disclose any significant financial interests to the official at their institution who is responsible for reviewing such disclosures.¹⁹ The institutional official then determines whether the investigator's significant financial interest is related to his or her institutional responsibilities and if so, whether the significant financial interest constitutes an FCOI. To meet this requirement, the University requires each investigator to complete an Outside Interest Disclosure.²⁰ This disclosure is a formal statement that identifies relevant information about outside interests that reasonably appear related to the investigator's

¹⁵ Federal regulations at 42 CFR § 50.603 define "financial conflict of interest (FCOI)" and "significant financial interest." See also Appendix B for more information on this requirement.

¹⁶ NIH, "Financial Conflict of Interest." Available online at <https://grants.nih.gov/grants/policy/coi/index.htm> (accessed on Jun. 25, 2019). The passage quoted was in effect during our audit period. After our audit period, NIH revised the passage on this webpage by removing the second quoted sentence.

¹⁷ 42 CFR § 50.604(d).

¹⁸ 42 CFR § 50.605(b).

¹⁹ 42 CFR § 50.604(e)(1). See also Appendix B for NIH's more detailed guidance on this requirement.

²⁰ This requirement appears in the University's *Individual Outside Interest Policy*.

institutional responsibilities. Relevant Federal regulations state that if the institutional official identifies an FCOI, the official works with the Investigator to implement a management plan to eliminate the FCOI. If the FCOI is eliminated prior to the expenditure of NIH funds, the Institution is not required to submit an FCOI report to NIH. Otherwise, the FCOI shall provide an FCOI report to NIH (42 CFR § 50.605(b)(1)).

If an institution of higher education carries out the NIH-funded research through a subrecipient, it must take reasonable steps to ensure that any subrecipient investigator complies with FCOI requirements.²¹

In light of the responsibilities that institutions, investigators, and subrecipients bear when conducting NIH-funded research, NIH has disseminated additional guidance. Specifically, on March 30, 2018, NIH released a guide notice, *Financial Conflict of Interest: Investigator Disclosure of Foreign Financial Interests*, to remind the NIH extramural research community that it is critically important that investigators understand the applicability of the FCOI regulations, including that compliance with the regulations is a condition of funding.^{22, 23} Additionally, NIH clarified that although the regulation excludes certain income related to institutions of higher education and Federal, State, or local governmental agencies, these exclusions only apply to U.S. entities. Therefore, investigators, including subrecipient investigators, must disclose all financial interests received from a foreign institution of higher education or governments of another country.²⁴

NIH Division of Grants Compliance and Oversight

The NIH Division of Grants Compliance and Oversight (DGCO) monitors external compliance with NIH policy and legislative mandates and enhances compliance oversight by recipient institutions. DGCO also ensures and evaluates the management of extramural resources.

In 2012, DGCO established the Proactive FCOI Compliance Oversight Program (FCOI compliance program) as a component of NIH's oversight responsibilities to assess institutional implementation of the FCOI regulations and ensure recipient compliance.²⁵ Under the FCOI

²¹ 42 CFR § 50.604(c).

²² Guide notices are released on the NIH Guide for Grants and Contracts page of NIH's website. Compliance with guide notices is a term and condition of awards. Each year, NIH incorporates the essential features of these notices into the annual update of the *NIH Grants Policy Statement*.

²³ *Financial Conflict of Interest: Investigator Disclosure of Foreign Financial Interests* (NOT-OD-18-160), Mar. 30, 2018.

²⁴ [Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components](#) (NOT-OD-19-114), Jul. 10, 2019).

²⁵ Proactive Compliance Oversight Program—Financial Conflict of Interest Requirements for NIH-Supported Institutions (NOT-OD-12-159), Sep. 21, 2012.

compliance program, DGCO assists institutions in developing and implementing their FCOI policies by reviewing and providing feedback on institutions' publicly accessible FCOI policies. NIH's FCOI compliance program seeks to address compliance with the FCOI regulations by providing oversight of institutions' implementation and maintenance of FCOI policies and procedures.²⁶ The objective of the FCOI compliance program is to review publicly accessible FCOI policies for a sample of NIH institutions. If there are deficiency areas, NIH expects the institutions to formally address and resolve all identified issues.

Saint Louis University

The University is located in Saint Louis, Missouri. The University was founded in 1818 and provides 15 graduate and undergraduate programs to almost 13,000 students each year. The University's Office of Vice President of Research is responsible for managing awards and for post-award compliance support.

For our audit period (January 1, 2017, through December 31, 2019), the University received 795 NIH awards, some of which were new awards and some of which were continuations of previous awards. For each new NIH award that it receives, the University creates an "award fund account" to track associated revenues and costs. (If an NIH award is a continuation of a previous award, a new award fund account is not created.) The University used 500 award fund accounts to manage and account for the 795 NIH awards it received during our audit period.

As part of its policies and procedures, the University contracted with an independent accounting firm to conduct internal audits of its policies and procedures. To comply with Federal regulations at 45 CFR part 75, the University received Single Audits each year of our audit period (footnote 5). In addition, the University created a compliance department in February 2019 to conduct oversight of its policies and regulations.

HOW WE CONDUCTED THIS AUDIT

Our audit covered costs totaling \$66,993,121 associated with the 795 NIH awards (managed in 500 award fund accounts) that the University received between January 1, 2017, and December 31, 2019.

We reviewed the University's policies and procedures to determine whether the University had controls in place during our audit period to ensure the allowability of costs in accordance with Federal and award requirements. We judgmentally selected 5 of the University's 500 award fund accounts, from which we judgmentally selected and reviewed 31 individual costs totaling \$426,443 that the University charged to the awards; these included time and effort reports for salary and wage costs, calculated fringe benefit costs, travel costs, direct costs, calculated

²⁶ 42 CFR § 50.604.

indirect costs, and subrecipient subawards.²⁷ We tested the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any limitations or exclusions.

To address our second objective, we reviewed policies and procedures the University had in place during our audit period for ensuring that employees received adequate FCOI training and that outside interest disclosures were sufficiently monitored to meet FCOI requirements. We judgmentally selected 30 employees from a list of employees whose salaries were charged to an NIH award, to test whether the University's policies and procedures ensured that employees had received the required training and that the University had conducted the appropriate FCOI reviews and reporting pursuant to the requirements in its policies and procedures for training and monitoring.²⁸

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains details of our audit scope and methodology.

FINDINGS

The University did not always manage NIH awards in accordance with Federal and award requirements. Specifically, of the 31 judgmentally selected costs totaling \$426,443 that we reviewed, we determined that 6 costs totaling \$42,578 did not comply with Federal and award requirements for allowability of costs. These errors occurred because the controls that the University had in place, to include policies and procedures, were inadequate to ensure that the University always managed its NIH awards in accordance with Federal and award requirements.

²⁷ We judgmentally selected the 5 award fund accounts based on the amounts of the costs charged to the NIH awards or the amounts of the awards that were passed through to subrecipients. We selected: (1) two award fund accounts that had the most expenditures reported during our audit period, (2) two award fund accounts that had the next two largest expenditures reported by the University and that included U.S. citizens and non-U.S. citizens as investigators, and (3) one award fund account that was included in the 2017 Single Audit finding. These award fund accounts accounted for almost 9 percent (\$5,771,661) of total direct expenditures and 27 percent (\$1,581,850) of passed-through expenditures incurred directly by the University. We judgmentally selected the 31 individual costs from the 5 award fund accounts, based on the dollar amount of the costs.

²⁸ We judgmentally selected the 30 employees with the highest salaries from the: (1) 5 award fund accounts from which we selected the 31 individual costs (footnote 27), (2) 5 award fund accounts that had the highest expenditures and that included U.S. citizen and non-U.S. citizen investigators, (3) 1 award fund account that was related to an award that started in our audit period, and (4) 1 award fund account that was included in the 2017 Single Audit finding.

For our second objective, we determined that the University had policies and procedures in place that were designed to meet FCOI requirements for training and monitoring of outside interest disclosures. Specifically, the University properly maintained training records and monitored outside interest disclosures to meet FCOI requirements associated with the 30 judgmentally selected employees.

Furthermore, while reviewing the University's financial management controls over these costs that were related to the NIH grant awards, we determined that the University's controls, including policies and procedures, were not always sufficient to ensure that it properly monitored subawards to identify possible investigator misconduct that may have impacted the conduct or performance of another NIH award. Although our review of payments to subrecipients identified no errors, we found that of the 31 judgmentally selected costs we reviewed (2 of which were subrecipient costs), 1 subrecipient cost was associated with possible subrecipient investigator misconduct in an unrelated NIH award not associated with the University. Therefore, the University's controls for subrecipient monitoring can be improved.

NOT ALL OF THE UNIVERSITY'S CLAIMED NIH AWARD COSTS COMPLIED WITH FEDERAL AND AWARD REQUIREMENTS

The University did not always manage NIH awards in accordance with Federal and award requirements. Of the 31 judgmentally selected costs totaling \$426,443 (from the 5 judgmentally selected award fund accounts (footnote 27)) that we reviewed, we determined that 6 costs totaling \$42,578 did not comply with the Federal and award requirements for allowability of costs.

The table on the following page details the costs that we sampled and the number of errors we identified for each cost category.

Table: Summary of Deficiencies in Sample Items

Cost Categories	Number of Costs Sampled	Total Amount Sampled	Number of Errors	Total Amount of Errors
Salary and Wage Costs	5	\$42,315	5	\$42,315
Fringe Benefit Costs	7	16,037	-	-
Travel Costs	5	7,636	1	263
Direct Costs	10	14,773	-	-
Indirect Costs	2	198,811	-	-
Subrecipient Subawards²⁹	2	146,871	-	-
Total	31	\$426,443	6	\$42,578

Federal and Award Requirements

Under the provisions of 45 CFR § 75.303(a) and the *NIH Grants Policy Statement*, section 8.3, recipients conducting NIH-supported research are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of the award.

The six selected costs summarized above and discussed below did not comply with these Federal and award requirements.

For details on Federal regulations and NIH award requirements, see Appendix B.

Employee Salary and Wage Costs

All five of the costs associated with the employee salary and wage items that we sampled, totaling \$42,315, contained errors (some sampled items contained more than one error).³⁰ Specifically:

- Four sampled items included 14 payroll costs in which the amounts paid did not reconcile to the University’s approved salaries or wages for those employees.

²⁹ We separately discuss our finding related to one of the subrecipient awards later in this report.

³⁰ For this cost category, a sampled item consisted of all salary and wage (i.e., payroll) costs that were charged to an NIH grant on a sampled date.

- Two sampled items included 19 time and effort reports that were certified by the employees more than 5 months after the end of the reporting periods. The University requires time and effort reports to be completed and certified for every 6-month period (i.e., for the periods ending June 30 and December 31 of each year); however, the University's policy does not specify how soon after the reporting period ends that employees must certify their time and effort reports. We identified 19 time and effort reports that covered the 6-month periods ending June 30 of each year of our audit period, which were not certified until more than 5 months after the ends of the reporting periods. When time and effort reports are not certified until months have passed since the end of their reporting periods, there is a risk that associated costs that the University claimed do not accurately reflect the resources actually allocated to performance of the NIH awards, potentially charging more costs to a grant award than were warranted.
- Two sampled items included eight payroll costs that were not included in the University's payroll reports. As part of our testing, we obtained a report of all paid payroll costs that were applied to award fund accounts and attempted to reconcile those costs to payroll reports. We identified eight payroll costs that were applied to award fund accounts but that could not be reconciled to the University's payroll reports.

We provided information on these 8 sampled items to the University for further research and explanation; however, the University did not provide an explanation as to why the: (1) 14 payroll costs did not reconcile to the University's approved salaries or wages for those employees, (2) University's policy did not specify how soon after the reporting period ends that employees must certify their time and effort reports, or (3) 8 payroll costs that were applied to award fund accounts could not be reconciled to the University's payroll reports.

Travel Costs

One of the 5 travel costs we reviewed, totaling \$263, contained an error for an unallowable hotel stay. (For this cost category, a sampled item consisted of all expenses applied to NIH award funds from a sampled travel voucher.) A University employee booked a hotel stay to attend a conference for 3 nights; however, the employee stayed at the hotel for only 2 nights and returned to the University on the third day. The employee's travel authorization forms and flight reservations showed that the employee intended to stay only 2 nights. The hotel charged all 3 nights to the employee; the voucher that the employee submitted to the University for reimbursement reflected a hotel stay of 3 nights; in turn, the University claimed the costs for 3 nights' lodging to an NIH award. University officials told us that they were not aware of this error until we brought it to their attention; they agreed with us that the third night of the hotel stay should not have been charged to the award. Because this error points to a shortcoming in the University's management of NIH awards, we are recommending a recovery of these funds.

Inadequate Financial Management Controls Contributed to the Cost Errors

The University's financial management controls were inadequate to ensure that it managed and used its NIH awards in accordance with Federal and award requirements, and contributed to the errors we identified. The University did not provide reasonable assurance that it consistently managed NIH awards in accordance with Federal and award requirements.

For example, the University's policies did not specify a timeframe in which time and effort reports were to be certified in order to account for the amount of time and effort that contributed directly to an award. Although the University's policy requires time and effort reports to be completed and certified for the periods ending June 30 and December 31 of each year, the policy does not specify a deadline for submission of those reports. As a result, the University could not ensure that required reports were submitted timely and accurately after completion of each 6-month reporting period. NIH award recipients are allowed a specified period of time to submit required financial and final progress reports.³¹ Specifically, annual reports are typically due 90 calendar days after the end of the reporting period; quarterly or semiannual reports are due 30 calendar days after the end of the reporting period.³² We found that the University's controls were inadequate to ensure that employees completed, certified, and submitted their time and effort reports so that the University could meet the NIH-established reporting due dates. Based on our review, we determined that time and effort reports were submitted between 139 and 208 calendar days after the awards' reporting periods; this range of time exceeded the 90 calendar days reporting period due date. The University did not have controls in place to monitor and track a timeframe in which time and effort reports were to be certified and submitted to ensure that the University could meet the NIH-established reporting due dates.

Furthermore, the financial management controls that the University had in place, to include its policies and procedures, were not sufficient for the University to complete a thorough review of costs claimed for its NIH awards to ensure that all costs met Federal and award requirements. This financial management shortcoming manifested itself even though the University had three different means that it could have used to review NIH award costs: internal audits, the University's compliance department, and Single Audits. First, as part of its policies and procedures, the University contracted with an independent accounting firm (internal audit firm) to conduct internal audits of its policies and procedures. Second, in February 2019 (which was during our audit period), the University created a compliance department to conduct oversight of its policies and regulations. However, during our audit period neither the internal audit firm nor the University's compliance department completed a review of costs that the University claimed for its NIH (and other Federal) awards. The policies and procedures that the University had in place did not specify timeframes or frequencies for completion of either the internal audits or the compliance department's oversight activities.

³¹ *NIH Grants Policy Statement*, section 8.4.1.

³² 45 CFR §§ 75.341 and 75.342(b)(1).

The third possible means by which the University could review NIH award costs is through annual Single Audits, in accordance with Federal regulations at 45 CFR part 75, from a third-party accounting firm.³³ During our audit period, the University received a Single Audit for each FY from 2017 through 2019. From our review of the three separate audit reports, we noted that the FY 2017 Single Audit conveyed a finding on inaccurate reporting of Federal expenditures on the Schedule of Expenditures for Federal Awards and a real property management finding involving some missing equipment.³⁴ Yet neither the internal audit firm nor the University's compliance department utilized these FY 2017 Single Audit report findings (or any information from the FYs 2018 or 2019 Single Audit reports) to inform their approach to independently review NIH award costs (or other Federal grant award costs).

The results of the Single Audits provided an opportunity for the internal audit firm to define the scope and nature of its internal audits, and for the compliance department to structure its own oversight activities, so as to include NIH and other Federal awards. The University did not, however, take advantage of this opportunity. Instead, staff from the internal audit firm told us that the firm did not review costs charged to Federal awards because it believed sufficient oversight of those costs had occurred when they were included in the scope of the Single Audits.³⁵ However, the internal audit firm's staff did not provide us with any support that the firm performed audit steps to identify which NIH (or other Federal) awards were subject to testing in the Single Audits. Accordingly, the internal audit firm did not give us evidence that it had determined that the scope of the FYs 2017 through 2019 Single Audits would satisfy the objectives of the internal audits insofar as the NIH award costs were concerned. Because the University excluded the NIH (and other Federal) grant awards from its internal audit review, the University sustained vulnerabilities in its financial management internal control structure.

The University would benefit from a robust financial management control structure, which includes a review of NIH grant award costs, when designing and implementing internal audits and compliance department oversight. Utilizing this approach would complement existing processes when examining the University's management and use of Federal funds and would build upon the annual Single Audit results rather than relying solely on the work performed as part of the Single Audits, as these are limited in terms of the amount of testing and the internal controls analysis performed to examine NIH grant awards. Because of the shortcomings we identified in the University's three different means that it could have used to review NIH award costs—internal audits, the University's compliance department, and Single Audits—its existing

³³ The accounting firm that performed the Single Audit was not the same audit firm with which the University contracted to perform the internal audits of its policies and procedures.

³⁴ The University's FY 2018 and 2019 Single Audits did not have any findings.

³⁵ While Single Audits provide insights regarding an entity's financial management operations and stewardship of Federal funds, they are not designed to identify all issues of noncompliance with Federal requirements, but rather, to determine whether an entity is materially in compliance. For this reason, Single Audits are limited in terms of the amount of testing that they conduct and the internal controls analysis that they perform; stated differently, Single Audits in and of themselves are not sufficient to substitute for strong internal controls on the part of the audited entity.

financial management controls were inadequate to ensure that costs charged to Federal awards were in accordance with Federal and award requirements. These inadequate controls were evident in the six sampled costs' errors totaling \$42,578 that did not meet NIH requirements for allowability of costs in accordance with Federal and award requirements.

THE UNIVERSITY HAD ADEQUATE POLICIES AND PROCEDURES IN PLACE FOR FINANCIAL CONFLICT OF INTEREST TRAINING AND MONITORING FOR THE EMPLOYEES WE REVIEWED

For our second objective, we determined that the University had policies and procedures in place that were designed to meet FCOI requirements for training and monitoring of outside interest disclosures. The University's policies for FCOI training included requiring each investigator to complete FCOI training: before engaging in research related to any Public Health Service awards and at least every 4 years; immediately after the University updates its FCOI policies and procedures; or if the investigator is new to the University. The University's policies for monitoring outside interest disclosures included a requirement that each investigator submit "a formal statement that identifies relevant information about outside interests that reasonably appear related to the individual's institutional responsibilities." The University's policies also require University officials to evaluate disclosures in relation to the investigator's institutional responsibilities and determine whether an FCOI exists (footnote 20). The University properly maintained training records and monitored outside interest disclosures to meet FCOI requirements associated with the 30 judgmentally selected employees.

Federal and Award Requirements

Federal conflict-of-interest regulations state: "HHS awarding agencies must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the respective HHS awarding agency or pass-through entity in accordance with applicable HHS awarding agency's policy" (45 CFR § 75.112).

According to the *NIH Grants Policy Statement*, section 4.1.10, "Financial Conflict of Interest," institutions must maintain an up-to-date written, enforced FCOI policy and post the policy on their publicly accessible websites.

For details on Federal regulations and award requirements, see Appendix B.

Financial Conflict of Interest Training and Monitoring Policies and Procedures Were in Place

The University had adequate policies and procedures in place to ensure that employees received adequate FCOI training and that the University adequately monitored outside interest disclosures to meet FCOI requirements. We judgmentally selected 30 employees to verify whether the University maintained up-to-date training records and outside interest disclosures for each employee. We determined that each employee had met the FCOI training requirements. We also determined that each employee had signed a current outside interest disclosure, and that the University had conducted the appropriate FCOI reviews and reporting

pursuant to the requirements in its policies and procedures for monitoring. On the basis of our review of supporting documentation, for the 30 judgmentally selected employees, we determined that the University had adequate policies and procedures in place to ensure that those employees received adequate FCOI training and that the University adequately monitored outside interest disclosures to meet FCOI requirements.

THE UNIVERSITY'S CONTROLS FOR SUBRECIPIENT MONITORING CAN BE IMPROVED

During our review of the University's financial management controls over costs related to the NIH grant awards discussed above, we determined that the University's controls, including policies and procedures, were not always sufficient to ensure that it properly monitored subawards to identify possible subrecipient investigator misconduct that may impact the conduct or performance of another NIH award. Specifically, of the 31 judgmentally selected costs we reviewed (2 of which were subrecipient costs), 1 subrecipient cost was associated with a case of possible subrecipient investigator misconduct on an NIH award not associated with the University. The University's monitoring did not identify the possible misconduct of the subrecipient's investigator.

NIH Policy Regarding Investigator Misconduct

A subrecipient is a non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; this classification does not apply to an individual who is a beneficiary of a Federal program. According to the *NIH Grants Policy Statement*, "[w]hen the recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of an NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH" (chapter 4.1.27).

The University's Monitoring Did Not Identify Possible Research Misconduct on the Part of a Subrecipient's Investigator

The University has policies and procedures for monitoring subrecipients, including conducting a risk assessment of a potential subrecipient. Additionally, the University's policies and procedures required that its subrecipient monitor for activities as necessary to ensure compliance with Federal regulations. In accordance with its policies, the University completed an initial risk assessment in June 2018 and classified the subrecipient as medium risk.

Federal regulations for pass-through entities state that based on an assessment of risk posed by a subrecipient, additional monitoring tools may be used to ensure proper accountability and compliance with program requirements. However, we found no evidence that the University conducted any additional monitoring based on its initial risk assessment of this subrecipient.³⁶

³⁶ 45 CFR § 75.352(e).

Therefore, the University was not adequately able to assess the impact or possible impact of the alleged research misconduct of the subrecipient's investigator on SLU's own research award.

Specifically, during our review of the 31 judgmentally selected costs, we reviewed 2 subrecipient costs. One of these involved a research project for which the University contracted with another university as a subrecipient to fulfill part of the research. However, in March 2020, the subrecipient cancelled the contract without prior notice and explained to the University that its assigned faculty member was no longer participating in NIH-funded research. After receiving this information, the University notified NIH that the subrecipient was cancelling the contract, but it did not follow up with the subrecipient institution to obtain a detailed explanation or reason for the cancellation.

According to what the subrecipient told us, it cancelled the subaward contract with the University because the faculty member in question was under investigation by NIH for alleged research misconduct on a different NIH award not associated with the University. According to the subrecipient, the subrecipient faculty member may also have had undisclosed affiliations with and compensation from foreign organizations.³⁷ As a result of these allegations, NIH requested (in May 2019) that the subrecipient's faculty member not be allowed to participate further in NIH-funded research. Although the subrecipient did not initially disclose the existence or results of the investigation to the University, the subrecipient's representatives told us that they would have provided the reason for the contract termination if the University had so requested. Although the University's own risk assessment had classified the subrecipient as a medium risk, the University did not take steps to inquire of the subrecipient as to the reasons for the no-notice cancellation of the contract. Because it did not follow up on the reason for the cancellation of the contract between the University and the subrecipient, the University was not adequately able to assess the impact or possible impact of the alleged research misconduct of the subrecipient's faculty member on the University's own research award.

The University's Controls Did Not Identify Possible Subrecipient Research Misconduct

The University did not identify the alleged research misconduct on an unrelated NIH award and undisclosed affiliations and compensation from foreign organizations by the faculty member working on the subaward, because the controls the University had in place, to include policies and procedures, were inadequate. Federal regulations allowed for the University to use additional monitoring tools to ensure proper accountability and compliance with program requirements; however, we found no evidence that the University conducted any additional monitoring of this subrecipient (footnote 36). Additionally, the policies and procedures did not

³⁷ Affiliations occur when one company or person controls or has the power to control another company or person. Institutions may take into account factors such as ownership, management, contractual relationships, and previous relationships with or ties to another concern (i.e., another entity) when determining whether an affiliation exists. At NIH, the term "affiliate" has the meaning set forth in 13 CFR section 121.103(a)(2). See <https://grants.nih.gov/grants/glossary.htm#Affiliate> for NIH's use of the term.

direct University staff to follow up with the subrecipient once the University had become aware of the cancellation of the subaward contract.

RECOMMENDATIONS

We recommend that Saint Louis University:

- refund \$263 to NIH for unallowable travel costs;
- ensure that it always manages NIH awards in accordance with Federal and award requirements by:
 - strengthening procedures for reconciliation of payroll costs to approved salaries and wages and to payroll reports, and
 - strengthening controls to ensure the timely completion and certification of employee time and effort reports after completion of each 6-month reporting period;
- enhance its existing controls by developing and implementing policies and procedures to ensure that either the internal audits conducted by its internal audit firm, the University's compliance department, or both, review costs that the University claims for its NIH awards; and
- strengthen its controls, to include policies and procedures, to ensure that it properly monitors its subaward subrecipients, to include:
 - evaluating its current risk assessment policies and procedures and implementing procedures to improve monitoring of subrecipients classified as high or medium risk and
 - developing and implementing notification and followup procedures to be executed in cases of subrecipient subaward or contract cancellation.

SAINT LOUIS UNIVERSITY COMMENTS

In written comments on our draft report, the University concurred with all of our recommendations and described corrective actions it had taken or planned to take. Specifically, in response to our first recommendation, the University stated that it had refunded to NIH the full amount of the unallowable travel expenditure and was "working to enhance our procedures and training on the submission, review, and approval of grant-reimbursable travel expenditures to prevent similar errors." With respect to our second recommendation, the University stated that its corrective response reflected changes to the University's systems, processes, personnel, and policy related to post-award grant management. The University

added that these changes included the introduction of a new automated financial system that “provides stronger controls, automates the link between payroll and effort certification, and ensures that all payroll costs tie to effort reports.” Other changes, according to the University, included the restructuring of its grants accounting function, the updating of the University’s effort certification policy, and (after implementation of the updated policy) the delivery of additional training to staff and faculty on time and effort reporting and certification requirements.

With respect to our third recommendation, the University stated that it has focused on updating University policies on a regular basis and specifically reviewing policies and procedures related to NIH funding. The University also stated that its compliance department would “continue to align its research compliance monitoring and spot audits with the internal audit firm, which as a result of the annual internal risk assessment, may conduct internal audits in the research area.” Additionally, the University said that it had engaged a consultant to assess and provide additional review and structural recommendations and that it had added a dedicated research compliance position as well as additional staff members who had been hired to review general expenditures charged to grants. “These investments demonstrate the University’s ongoing commitment to compliance with all NIH grant awards and Federal requirements.”

With respect to our fourth recommendation, the University stated that it had reorganized its contract and contract reporting functions, creating an office of research contracts with the Office of the Vice President for Research. This office is tasked with creating, monitoring, and reporting on all subawards, and performs an enhanced risk assessment each time it issues a new subaward. Furthermore, the University stated that its policy update will require followup actions, which the University described in its comments, in cases when subawards are canceled.

The University’s written comments appear in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered costs totaling \$66,993,121 associated with the 795 NIH awards (managed in 500 award fund accounts) that the University received between January 1, 2017, and December 31, 2019 (audit period).

We reviewed the University's policies and procedures to determine whether the University had controls in place during our audit period to ensure the allowability of costs in accordance with Federal and award requirements. We judgmentally selected 5 of the University's 500 award fund accounts, from which we judgmentally selected and reviewed 31 individual costs totaling \$426,443 that the University charged to the awards; these included time and effort reports for salary and wage costs, calculated fringe benefit costs, travel costs, direct costs, calculated indirect costs, and subrecipient subawards (footnote 27). We tested the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any limitations or exclusions.

To address our second objective, we reviewed policies and procedures the University had in place during our audit period for ensuring that employees received adequate FCOI training and that outside interest disclosures were sufficiently monitored. We judgmentally selected 30 employees from a list of employees whose salaries were charged to an NIH award, to test whether the University's policies and procedures ensured that employees had received the required training and that the University had conducted the appropriate FCOI reviews and reporting pursuant to the requirements in its policies and procedures for training and monitoring (footnote 28). Accordingly, we reviewed the University's policies and procedures for the following:

- vetting or background checks for all staff working on NIH grants,
- outside interest disclosure policy,
- FCOI training requirements,
- financial disclosure requirements (if separate from FCOI policy),
- specific policies related to staff who are not U.S. citizens,
- specific policies related to staff participating in any foreign talent or recruitment program, and
- identifying, selecting, and approving subrecipients of NIH grants.

We conducted our audit work from September 2020 to March 2023.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal regulations and NIH policies;

- reviewed NIH policies to determine whether the University: (1) had necessary controls in place to ensure allowability of costs in accordance with Federal and award requirements and (2) met FCOI requirements for training and outside interest disclosure monitoring;
- reviewed the University's policies and procedures for charging costs to Federal awards;
- discussed the FCOI regulations with University personnel to gain an understanding of the University's FCOI policies and procedures;
- met with the University's compliance department personnel and personnel from the internal audit firm to gain an understanding of risks that had been identified by the University relating to NIH awards and what reviews had been completed of NIH awards;
- met with two University Principal Investigators for NIH-awarded research to gain an understanding of how Principal Investigators monitor subrecipients;
- judgmentally selected 5 of the University's 500 award fund accounts (footnote 27);
- judgmentally selected and reviewed 31 individual costs totaling \$426,443 (footnote 27) that the University charged to the grant awards, which included time and effort reports for salary and wage costs, calculated fringe benefit costs, travel costs, direct costs, calculated indirect costs, and subrecipient subawards;
- tested the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any limitations or exclusions;
- obtained a report of all paid payroll costs that were applied to award fund accounts and attempted to reconcile those payments to payroll reports;
- reviewed the training records and outside interest disclosure agreements associated with 30 judgmentally selected employees (footnote 28);
- discussed our findings with the University officials on September 1, 2022;
- met with University officials on October 6, 2022, and received from them additional information in response to the findings we had discussed on September 1, 2022; and
- updated our findings based on information that was provided at our October 6, 2022, meeting with University officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL REGULATIONS AND GRANT AWARD REQUIREMENTS

FEDERAL REGULATIONS

The FCOI regulations at 42 CFR § 50.603 define a “financial interest” to mean “anything of monetary value, whether or not the value is readily ascertainable,” and a “significant financial interest” to be any financial interest of the investigator, the investigator’s spouse, and the investigator’s dependent children that reasonably appears to be related to the investigator’s “institutional responsibilities.”³⁸ A minimum threshold of \$5,000 for disclosure generally applies to most types of financial interests or to the total combined value of the financial interests. Intellectual property rights and interests (e.g., patents and copyrights), upon receipt of an unspecified amount, may constitute a significant financial interest.

The FCOI regulations at 42 CFR § 50.604 provide explanations of responsibilities of institutions regarding investigator FCOIs.

Federal regulations at 45 CFR § 75.403, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*, identify factors affecting allowability of costs. The tests of allowability of costs under these principles are that they must:

- (a) Be necessary and reasonable for the performance of the Federal award and be allocable thereto under these principles.
- (b) Conform to any limitations or exclusions set forth in these principles or in the Federal award as to types or amount of cost items.
- (c) Be consistent with policies and procedures that apply uniformly to both federally-financed and other activities of the non-Federal entity.
- (d) Be accorded consistent treatment. A cost may not be assigned to a Federal award as a direct cost if any other cost incurred for the same purpose in like circumstances has been allocated to the Federal award as an indirect cost.
- (e) Be determined in accordance with generally accepted accounting principles, except, for state and local governments and Indian tribes only, as otherwise provided for in this part.

³⁸ The definition of significant financial interest under the 1995 FCOI regulations was linked to an investigator’s responsibilities. The 2011 FCOI regulations broadened the definition of significant financial interest to include an investigator’s institutional responsibilities (examples of which include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels) (76 Fed. Reg. 53256, 53263 (Aug. 25, 2011)).

- (f) Not be included as a cost or used to meet cost sharing or matching requirements of any other federally-financed program in either the current or a prior period.
- (g) Be adequately documented.

Federal regulations at 45 CFR § 75.112 state:

- (a) HHS awarding agencies must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the respective HHS awarding agency or pass-through entity in accordance with applicable HHS awarding agency's policy. As a general matter, HHS awarding agencies' conflict of interest policies must:
 - (1) Address conditions under which outside activities, relationships, or financial interests are proper or improper;
 - (2) Provide for advance notification of outside activities, relationships, or financial interests, and a process of review as appropriate; and
 - (3) Outline how financial conflicts of interest may be addressed.
- (b) Agencies with Public Health Service (PHS)-funded research will ensure that any conflict-of-interest policies are aligned with the requirements of 42 CFR part 50, subpart F.

NIH Policies and Guidance Related to Financial Conflict of Interest

According to the *NIH Grants Policy Statement*, section 4.1.10, "Financial Conflict of Interest," institutions must maintain an up-to-date written, enforced FCOI policy and post the policy on their publicly accessible websites. This requirement applies to all NIH applicants and awardees, except for Small Business Innovation Research/Small Business Technology Transfer Research Phase I applicants and awardees.

Further guidance appears on the NIH FCOI webpage.³⁹

³⁹ Available online at [Financial Conflict of Interest | grants.nih.gov](https://www.grants.nih.gov/grants/financialconflict/) (accessed Mar. 2, 2023). NIH has made some changes in its guidance on FCOIs since the end of our audit period.



**SAINT LOUIS
UNIVERSITY**

— EST. 1818 —

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April 14, 2023

James I. Korn
Regional Inspector General for Audit Services
Office of Audit Services, Region VII
Office of Inspector General
Department of Health and Human Services
Room 0429
601 East 12th Street
Kansas City, MO 64106

RE: Report Number A-07-20-05127

Dear Mr. Korn:

Saint Louis University appreciated the opportunity to provide this letter in response to the Office of Inspector General's draft report, *Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements but Complied With Federal Conflict of Interest Requirements*, dated March 16, 2023.

We recognize that your audit of Saint Louis University was one of a series of audits of institutions of higher education that were recent grant recipients of the National Institutes of Health.

We appreciate the questions and observations posed by your team, as well as the opportunity to review and respond to your preliminary findings.

Saint Louis University is committed to enhancing our internal controls, policies, procedures and training to ensure that the University always manages NIH awards in accordance with Federal and award requirements.

Recommendation 1

[T]hat Saint Louis University refund \$263 to NIH for unallowable travel costs.

Saint Louis University concurs with the OIG's recommendation and recognizes that human error in processes resulted in \$263 being inappropriately charged as a grant-reimbursable travel expenditure.

On March 29, 2023, the University refunded to the NIH the full amount of the unallowable travel expenditure totaling \$263.

In addition, the University is working to enhance our procedures and training on the submission, review, and approval of grant-reimbursable travel expenditures to prevent similar errors.

Recommendation 2

[That Saint Louis University] ensure that it always manages NIH awards in accordance with Federal and award requirements by strengthening procedures for reconciliation of payroll costs to approved salaries and wages and to payroll reports and strengthening controls to ensure the timely completion and certification of employee time and effort reports after completion of each 6-month reporting period.

Saint Louis University concurs with the OIG's recommendation.

Our corrective response reflects the University's review and changes to systems, processes, personnel and policy related to post-award grant management.

During the period under audit, January 1, 2017, through December 31, 2019, the University operated separate financial and effort reporting systems, and performed a manual upload of data to initiate all effort certifications.

In 2019, the University decided to implement Workday across multiple areas of the University that included a new automated financial management system and an integrated effort reporting system.

On July 1, 2020, Saint Louis University introduced this new automated financial system that integrates effort certification into the payroll system. This system change provides stronger controls, automates the link between payroll and effort certification, and ensures that all payroll costs tie to effort reports.

As of October 2022, the University's grants accounting function moved to a newly created, staffed and trained unit within the Division of Business and Finance. In March 2023, the University undertook a broader review of its post-award grant management structure.

Saint Louis University's effort certification policy states that all reports must be completed within 30 days of initiation. The University is updating that policy to state that the effort certification must be launched within 60 days of the end of the period, ensuring that all effort certifications are completed within 90 days of the end of the period. Updates to the policy will be completed no later than June 30, 2023, and faculty and staff will receive additional training on time and effort reporting and certification requirements.

Recommendation 3

[That Saint Louis University] enhance its existing controls by developing and implementing policies and procedures to ensure that either the internal audits conducted by its internal audit firm,

the University's compliance department, or both, review costs that the University claims for its NIH award.

Saint Louis University concurs with the OIG's recommendation.

This audit focused on the time period of January 1, 2017, through December 31, 2019. Since that time, several units that are instrumental in managing and monitoring internal controls have matured.

The Office for University Compliance & Ethics was established in March 2019. Since then, the University's Policy Program has matured to include a focus on updating university policies on a regular basis. Through this process, the Office for University Compliance & Ethics has worked closely with the Office for the Vice President for Research to review policies and procedures related to NIH funding. The compliance office will continue to align its research compliance monitoring and spot audits with the internal audit firm, which as a result of the annual internal risk assessment, may conduct internal audits in the research area.

Additionally, in the Fall of 2021, SLU engaged a consultant to assess and provide additional review and structural recommendations. As part of that engagement, the University has added a dedicated research compliance position. This position was filled in January 2023 and has responsibility for research compliance functions.

The University continues to improve both its pro-active expense approval process and post-action reporting capabilities. In March 2023, the University undertook a broader review of its post-award grant management structure. Additional staff members have been hired to review general (non-payroll) expenditures charged to grants and reporting capabilities have been enhanced to allow PI's, department administrators and senior leadership to review costs that the University claims for its NIH awards.

These investments demonstrate the University's ongoing commitment to compliance with all NIH grant awards and Federal requirements. The University's three-tiered compliance structure includes a dedicated research compliance position, the Office for University Compliance & Ethics, and Internal Audit. This compliance structure, along with the University's broader review of its post-grant management structure, better enables the University to give additional attention to NIH costs, effort certification, financial conflict of interest, and subawards in its risk assessment process and audit plans.

Recommendation 4:

[That Saint Louis University] strengthen its controls, to include policies and procedures, to ensure that it properly monitors its subaward subrecipients, to include evaluating its current risk

assessment policies and procedures and implementing procedures to improve monitoring of subrecipients classified as high or medium risk and developing and implementing notification and follow up procedures to be executed in cases of subrecipient subaward or contract cancellation.

Saint Louis University concurs with this recommendation.

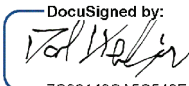
On July 1, 2022, Saint Louis University reorganized its contract and contract reporting functions, creating an office of research contracts with the Office of the Vice President for Research. This office is tasked with creating, monitoring, and reporting on all subawards. This office performs an enhanced risk assessment each time it issues a new subaward and includes language about monitoring in the contract, if needed.

The office is developing automated financial management reports to flag any medium- and high-risk subcontracts for regular management review. The University is currently reviewing and updating relevant policies and procedures based on these observations.

In addition, the University's policy update will require follow-up in cases where subcontracts are canceled. It will specify that University officials should request information from the subrecipient and document the reason for termination of a subcontract. In situations where the subrecipient fails or refuses to respond to an inquiry, the University will document its request(s) and any response(s). Updates to this policy will be completed no later than June 30, 2023.

Saint Louis University takes its compliance obligations seriously. As indicated above, we agree with OIG's recommendations and have made or initiated changes to University systems, processes, personnel, and policies to address the findings and recommendations from the audit.

Sincerely,

DocuSigned by:

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David Heimburger
Vice President and Chief Financial Officer