

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ILLINOIS STATE UNIVERSITY'S
MANAGEMENT OF NIH AWARDS
COMPLIED WITH FEDERAL AND
FINANCIAL CONFLICT OF INTEREST
REQUIREMENTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



**Amy J. Frontz
Deputy Inspector General
for Audit Services**

**September 2023
A-05-20-00033**

Office of Inspector General

<https://oig.hhs.gov>

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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: September 2023
Report No. A-05-20-00033

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 and cooperative agreements that it awards each year. This audit of Illinois State 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 over \$2 million associated with 17 NIH awards that the University received between October 1, 2016, and September 31, 2019. We selected a judgmental sample of 698 NIH award expenditures totaling \$1,234,300 and tested the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any limitations or exclusions. We also reviewed policies and procedures the University had in place for ensuring that employees received adequate FCOI training and that outside interest disclosures were sufficiently monitored to meet FCOI requirements.

Illinois State University's Management of NIH Awards Complied With Federal and Financial Conflict of Interest Requirements

What OIG Found

The University managed NIH awards in accordance with Federal and award requirements. We reviewed 698 expenditures totaling \$1,234,300 that the University charged to 5 awards, and we determined that the costs complied with Federal and award requirements.

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 disclosures of significant outside activity to meet FCOI requirements associated with the seven employees in our sample who had received NIH awards as Principal Investigator or Co-Principal Investigator.

What OIG Recommends and Auditee Comments

This report contains no recommendations.

In written comments on our draft report, the University accepted the report as written.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objectives.....	2
Background.....	2
NIH Award Funding.....	2
Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.....	3
NIH Grants Policy Statement.....	3
Financial Conflict of Interest Regulations.....	3
NIH Financial Conflict of Interest Reporting.....	4
NIH Division of Grants Compliance and Oversight.....	5
Illinois State University.....	6
How We Conducted This Audit.....	6
RESULTS OF AUDIT.....	7
The University’s Claimed NIH Award Costs Complied With Federal and Award Requirements.....	7
The University Had Adequate Policies and Procedures in Place To Meet Financial Conflict of Interest Requirements.....	8
CONCLUSION.....	9
AUDITEE COMMENTS.....	9
APPENDICES	
A: Audit Scope and Methodology.....	10
B: Federal Regulations and Award Requirements.....	12
C: The University Comments.....	15

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 (FFY) 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 award application and selection processes, and has reviewed NIH-funded research institutions' compliance with Federal requirements and NIH policies that establish controls for NIH awards, 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 awards 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 Illinois State University (the University) as a part of a series of audits of institutions of higher education, as a result of findings within 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, Apr. 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 Interests and Other Support*](#) (OEI-03-20-00210), June 2, 2022.

⁵ Under 45 CFR § 75.501(a), a non-Federal entity that expends \$750,000 or more Federal awards during an FY must be the subject of a Single 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 by the Public Health Service (PHS) or proposed for such funding. 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 Grant 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 Oct./Nov. 2015, Nov. 2016, Oct. 2017, and Oct. 2018; 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 July 15, 2019).

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 notes 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 a Public Health Services (PHS) FCOI disclosure of significant outside activity ("disclosure of significant outside activity").²⁰ This disclosure is a formal statement that identifies relevant information about outside interests that reasonably appear related to the investigator's institutional

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 June 29, 2022).

¹⁷ 42 CFR § 50.604(d).

¹⁸ 42 CFR § 50.605(b).

¹⁹ 42 CFR § 50.604(e)(1).

²⁰ This requirement appears in the University's *Research and Ethics Training Requirements*.

responsibilities. Relevant Federal regulations state if the institutional official identifies a 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 regulations exclude 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 subrecipients investigators, must disclose all financial interests received from foreign institutions 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), July 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 were deficiency areas, NIH expected the institutions to formally address and resolve all identified issues.

Appendix B contains the Federal Regulations and Grants Awards Requirements.

Illinois State University

The University is located in Normal, Illinois. It was founded in 1857 as the first public university in Illinois. The University received 17 NIH awards totaling over \$2 million during our audit period. NIH awards included, but not limited to, high-profile digital platforms, grant compliance, peer review, communications with the extramural community, scientific misconduct, human subjects protection, and laboratory animal welfare.

HOW WE CONDUCTED THIS AUDIT

Our audit covered 17 NIH awards for which the University was the recipient of the award funds. For these 17 awards, the University claimed expenditures totaling \$2,387,677 during the period of October 1, 2016, through September 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 allowability of costs in accordance with Federal award requirements during the audit period. We selected 5 of the 17 total awards during the audit period, and then we judgmentally selected and reviewed 698 expenditures totaling \$1,234,300 that the University charged to the awards, which included time and effort reports for salaries and wages, fringe benefit calculations, travel costs, direct costs, calculated 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 selected 7 employees from the population of 71 Principal Investigators and Co-Principal

²⁶ 42 CFR § 50.604.

²⁷ We judgmentally selected the five awards 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 judgmentally selected the 698 costs from the 5 award accounts, based on the amount of the costs.

Investigators whose salaries were charged to the NIH awards, 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.

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 the details of our audit scope and methodology.

RESULTS OF AUDIT

The University managed NIH awards in accordance with Federal and award requirements. We reviewed 698 expenditures totaling \$1,234,300 that the University charged to 5 awards, and we determined that the costs complied 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. Specifically, the University properly maintained training records and monitored disclosures of significant outside activity to meet FCOI requirements associated with the seven employees in our sample who had received NIH awards as Principal Investigator or Co-Principal Investigator.

THE UNIVERSITY’S CLAIMED NIH AWARD COSTS COMPLIED WITH FEDERAL AND AWARD REQUIREMENTS

The University claimed NIH award costs that complied with Federal and award requirements. We judgmentally selected and reviewed expenditures totaling \$1,234,300 that the University charged to the awards, which included time and effort reports for salaries and wages, fringe benefit calculations, in-state travel related costs, direct costs (including equipment, scientific and medical supplies), calculated indirect cost rates, and subrecipient subawards to other universities. The table below details the costs in each category.

Table: Cost Reviewed by Each Category

Cost Categories	Number of Costs Reviewed	Total Cost Amount
Salary/wages & fringe benefits	520	\$712,257.34
Travel costs	10	23,487.02
Direct costs	18	35,597.99
Indirect costs	148	434,351.36
Subrecipient subawards	2	28,606.29
Total	698	\$1,234,300

The five selected cost categories summarized above comply with the following Federal and award requirements.

The University had controls in place to ensure allowability of costs in accordance with Federal and award requirements. For example, the University had (1) written policies and procedures for the use and management of Federal funds; (2) an award management division that reviewed grant costs to ensure OMB uniform guidelines were followed; and (3) periodic outreach with principal investigators responsible for the preparation, conduct, and administration of their sponsored project awards. 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. To be allowable under Federal awards, costs must be necessary, reasonable, and allocable (45 CFR § 75.403(a)).

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

THE UNIVERSITY HAD ADEQUATE POLICIES AND PROCEDURES IN PLACE TO MEET FINANCIAL CONFLICT OF INTEREST 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 investigators' disclosures of significant outside activity. The University's policies for FCOI training included requiring each investigator to complete FCOI training. The University's policies for monitoring outside interests included a requirement that each investigator submit a disclosure of significant outside activity.

The University policy requires disclosure of significant outside activities held by the principal investigator/project director, co-principal investigators, and any other persons at the university who are responsible for the design, conduct, assessment, and/or reporting of research, educational, or service activities funded (or proposed for funding) by an external sponsor and their immediate family members. A University official designee conducts an initial review of all significant outside activity disclosures to determine whether a FCOI may exist. The University stated that it had no NIH FCOI disclosures during our audit period. Utilizing OIG data analytics, we were able to confirm that no FCOI disclosures were submitted to NIH during our audit period.

Financial 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. Grantee institutions must certify that they have written and enforced administrative processes to identify and manage, reduce, or eliminate FCOIs.

CONCLUSION

Based on our audit results, this report contains no recommendations.

AUDITEE COMMENTS

In written comments to our draft report, the University accepted the report as written.

The University's comments are included in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 17 NIH awards for which the University was the recipient. For these awards, the University claimed expenditures totaling \$2,387,677 million during the period of October 1, 2016, through September 31, 2019 (audit period).

To address our first objective, 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 a sample of 698 expenditures for the University and reviewed a total of \$1,234,300, which included time and effort reports for salaries and wages, calculated fringe benefit costs, travel costs, direct costs, calculated indirect costs, and subrecipient subawards. 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 FCOI reporting was sufficiently monitored. We also reviewed the training records and disclosure agreements of 7 employees we judgmentally selected from 71 University employees associated with the 5 NIH awards described above. We tested the University's FCOI requirements by obtaining and reviewing the University's policies and procedures for the following:

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

We conducted our audit work from May 2020 through August 2023.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal regulations and NIH guidelines;

- 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 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 Internal Audit contracted accounting 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;
- reviewed the University’s approved Indirect Cost Rate Plan;
- judgmentally selected 5 of the 17 awards and reviewed supporting documentation for 698 expenditures totaling \$1,234,300, which included time and effort reports for salaries and wages, fringe benefit calculations, travel costs, direct costs, indirect cost calculations, and subrecipient subawards (footnote 27);
- 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 the 5 selected award fund accounts and reconciled those payments to payroll reports;
- reviewed the training records and disclosure agreements of 7 employees we judgmentally selected from the 5 awards selected from the 17 NIH awards; and
- discussed the results of our audit with the 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 AWARD REQUIREMENTS

FEDERAL REGULATIONS

The FCOI regulations at 42 CFR § 50.603 define a “financial interest” to mean anything of monetary value. A “significant financial interest” is 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.”²⁸ 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) 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 42 CFR § 50.605(b)(1) state:

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

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

²⁸ 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)).

(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.

Federal regulations at 45 CFR § 75.303 internal controls state:

The non-Federal entity must:

- (a) Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award. These internal controls should be in compliance with guidance in “Standards for Internal Control in the Federal Government,” issued by the Comptroller General of the United States or the “Internal Control Integrated Framework,” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
- (b) Comply with Federal statutes, regulations, and the terms and conditions of the Federal awards.
- (c) Evaluate and monitor the non-Federal entity's compliance with statutes, regulations, and the terms and conditions of Federal awards.
- (d) Take prompt action when instances of noncompliance are identified including noncompliance identified in audit findings.
- (e) Take reasonable measures to safeguard protected personally identifiable information and other information the HHS awarding agency or pass-through entity designates as sensitive or the non-Federal entity considers sensitive consistent with applicable Federal, state, local, and tribal laws regarding privacy and obligations of confidentiality.

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.
- (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.

NIH Policies and Guidance

According to the *NIH Grants Policy Statement*, section 4.1.10, “Financial Conflict of Interest,” institutions must maintain an up-to-date written, enforced administrative process to identify and manage FCOI with respect to all research projects for which NIH funding is sought or received and post the policy on their publicly accessible websites. This rule applies to all NIH recipients and investigators, except for Small Business Innovation Research/Small Business Technology Transfer Research Phase I applicants and awardees.

Section 8.3 of the *NIH Grants Policy Statement* states:

Recipient organizations must establish and maintain effective internal controls to provide reasonable assurance that they are in compliance with Federal statutes, regulations, and terms and conditions of award (45 CFR 75.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (45 CFR 75.303(c)), and they must take prompt action when instances of noncompliance are identified (45 CFR 75.303(d)).

Further guidance appears on the NIH FCOI webpage.²⁹

²⁹ Available online at [Financial Conflict of Interest | grants.nih.gov](https://grants.nih.gov/financial-conflict-of-interest/) (accessed Feb. 17, 2023). NIH has made some changes in its guidance on FCOIs since the end of our audit period.

APPENDIX C: AUDITEE COMMENTS



Tuesday, August 29, 2023

Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Report A-05-20-00033

On behalf of The Board of Trustees of Illinois State University, I am confirming that Report A-05-20-00033 has been reviewed and is acceptable as written.

Thanks for the opportunity to provide a response to this report.

Kind Regards,

/Craig C. McLauchlan/

Craig C. McLauchlan
Associate Vice President for Research and Graduate Studies