

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NEW YORK MEDICAL COLLEGE
CLAIMED UNALLOWABLE GRANT
COSTS AND DID NOT MEET CERTAIN
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

May 2024
A-04-20-03583

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

Office of Audit Services. OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

Office of Counsel to the Inspector General. OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and civil monetary penalties, monitors Corporate Integrity Agreements, and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, the anti-kickback statute, and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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: May 2024

Report No. A-04-20-03583

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 New York Medical College (the College) is part of a series of audits of institutions of higher education.

Our objectives were to determine whether the College (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 more than \$17 million associated with 24 NIH awards in effect at the College from October 1, 2017, through September 30, 2019.

We reviewed the College's policies and procedures to determine whether it had controls to ensure costs met Federal and award requirements. We judgmentally selected for review 92 transactions totaling \$143,508.

To address our second objective, we judgmentally selected 35 financial FCOI disclosure forms and training certificates to test whether the College complied with FCOI requirements for completing FCOI disclosure reports and training.

New York Medical College Claimed Unallowable Grant Costs and Did Not Meet Certain Financial Conflict of Interest Requirements

What OIG Found

Prior to July 2019 the College used budget estimates instead of actual activity to claim \$7.5 million in salaries, fringe benefits, and indirect costs. Specifically, the College's system and procedures for accounting for personal services costs did not produce records that reasonably reflected the actual activity for which employees were compensated. We also found that subsequent to July 2019, the College created time and effort certification reports that contained illegible signatures or were not dated. The College also charged unallowable costs totaling \$73,515 to its NIH awards because it did not have policies and procedures, or it did not follow existing policies and procedures to ensure that costs charged to NIH awards were reasonable, allocable, and allowable.

In addition, the College did not meet certain FCOI requirements. Specifically, the College could not verify that 7 of 14 key individuals assigned to NIH awards completed required FCOI training and that 9 of the 14 key individuals completed required FCOI disclosure forms. These errors occurred because the College did not have adequate controls to ensure that key individuals assigned to NIH awards completed required FCOI training and completed disclosure forms annually.

What OIG Recommends and College Comments

We recommend that the College work with NIH to determine the allowability of \$7,469,306 in salaries, fringe benefits, and related indirect costs that were unsupported and refund \$73,515. We also recommend the College strengthen its systems and procedures for identifying unsupported and unallowable costs and ensuring that certain FCOI requirements are met. Additionally, we made eight internal control recommendations.

In its written comments, the College generally disagreed with our three findings but it agreed with the majority of our recommendations. The College agreed to work with NIH to determine the allowability of the \$7.5 million and to refund any overpayments. The College agreed that \$37,533 of the \$73,515 was unallowable costs and that it would improve monitoring of FCOI training and disclosure forms. Of 8 internal control recommendations, the College agreed with 6, partially agreed with 1, and disagreed with 1. It provided additional documentation supporting \$113 in previously disallowed direct travel costs (\$69) and related indirect costs (\$44), and we reduced our second finding and recommendation from \$73,628 to \$73,515. We also revised certain language in our third finding.

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
New York Medical College	6
How We Conducted This Audit	6
FINDINGS	7
The College Claimed Salary and Related Costs Using Budget Estimates.....	9
Federal Requirements.....	9
Pre-July 2019 Effort Reporting Process	9
Post-July 2019 Effort Reporting Process.....	11
The College Claimed Unallowable NIH Award Costs	12
Salary Costs That Exceeded NIH’s Salary Cap	12
Contingent Salary Increase	14
Cost Transfers	15
The College Claimed Some Travel Costs That Were Unallowable or Undocumented	16
Federal Requirements.....	16
Unallowable Travel Costs.....	17
Unsupported Travel Costs.....	17
Policies and Procedures Were Not Followed or Were Lacking in Some Instances to Ensure That Costs Were Allowable	17
The College Did Not Always Meet Certain Financial Conflict of Interest Requirements	18
RECOMMENDATIONS	19

NEW YORK MEDICAL COLLEGE COMMENTS AND OIG RESPONSE	20
The College Claimed Salary and Related Costs Using Budget Estimates.....	20
The College Claimed Unallowable NIH Award Costs	22
The College Did Not Always Meet Certain Financial Conflict of Interest Requirements	23
APPENDICES	
A: Audit Scope and Methodology	25
B: Federal Regulations and NIH Award Requirements	27
C: College Policy Excerpts	31
D: College’s Comments.....	33

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 award application and selection processes, and it 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 that 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 In addition, 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 New York Medical College (the College), as part of a series of audits⁵ of institutions of higher education, and based on our risk assessment of the College.

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 online at https://oig.hhs.gov/documents/testimony/316/Gary_Cantrell_Testimony_Senate_HELP_Foreign_Influence.pdf. Accessed on Nov. 1, 2022. 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) Sept. 25, 2019.

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

⁵ *Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements but Complied With Financial Conflict of Interest Requirements* (A-07-20-05127), June 1, 2023, and *Illinois State University's Management of NIH Awards Complied With Federal and Financial Conflict of Interest Requirements* (A-05-20-00033) Sept. 26, 2023.

OBJECTIVES

Our objectives were to determine whether the College: (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 managing any FCOIs and reporting them to NIH.⁷

The institution must report FCOIs 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 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 (42 CFR § 50.605(b) and *NIH Grants Policy Statement*, section 4.1.10).

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* (NIHGPS) makes available, in a single document, the policy requirements that serve as the terms and conditions of NIH awards. Accordingly, the NIHGPS 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 each institution that applies for or receives research funding from NIH to make its FCOI policy available on a publicly accessible website.¹⁰ This final rule built on 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* 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)." Available online at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>. Accessed on Sept. 22, 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 interest. 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 FCOIs 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 their institutional responsibilities and if so, whether the significant financial interest constitutes an FCOI. To meet this requirement, the College requires that a faculty member or other investigator who plans to participate in proposed research and other sponsored projects must

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/loi/index.htm>. Accessed on Sept. 22, 2023. 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).

have completed and submitted an annual conflict of interest disclosure form.^{20, 21} This disclosure is a formal statement that identifies relevant information about outside interests that appear reasonably related to the investigator's 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 before the expenditure of NIH funds, the institution is not required to submit an FCOI report to NIH. Otherwise, the institutional official shall provide an FCOI report to NIH.²²

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.²³

Considering 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.^{24, 25} In addition, 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.²⁶

²⁰ This requirement appears in the College's *Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment*, dated May 31, 2012.

²¹ Effective Dec. 22, 2020, the College revised its conflict-of-interest policy and made it applicable to all members of the College community, including but not limited to trustees, officers, and administrators, employed faculty, voluntary faculty, and other full-time and part-time employees of the College.

²² 42 CFR § 50.605(b)(1).

²³ 42 CFR § 50.604(c).

²⁴ Guide notices are released in the *NIH Guide for Grants and Contracts*. Available at <https://grants.nih.gov/funding/searchguide/index.html#/>. Accessed on Mar. 20, 2024. 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*.

²⁵ *Financial Conflict of Interest: Investigator Disclosure of Foreign Financial Interests* (NOT-OD-18-160), Mar. 30, 2018.

²⁶ *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.

New York Medical College

The College, a member of the Touro College and University System, is a health sciences college whose purpose is to educate clinical and public health professionals and researchers to conduct biomedical and population-based research. Since 1971, the College has been located on a 54-acre campus in Valhalla, New York. For the 2021–2022 academic year, the College’s enrollment totaled 2,002 students on campus and online. The College has five schools—Medicine, Health Sciences and Practice, Graduate School of Basic Medical Sciences, Touro College of Dental Medicine, and Touro College School of Health Sciences' Nursing Program.

HOW WE CONDUCTED THIS AUDIT

Our audit covered 24 NIH awards totaling \$17,172,846 that the College received between October 1, 2017, through September 30, 2019 (audit period).²⁷

We reviewed the College’s policies and procedures to determine whether the College 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 College’s 24 awards.²⁸ These 5 awards totaled \$3,154,423 and represented approximately 18 percent of the \$17,172,846 that NIH awarded to the College during our audit period. From these 5 awards we judgmentally selected 92 transactions totaling \$143,508 that the College charged to the awards.²⁹ 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 College had in place during our audit period for ensuring that employees received adequate FCOI training and completed required annual FCOI disclosure reports. We judgmentally selected 35 College and subrecipient employees’ FCOI disclosure forms and training certificates to test whether the College’s policies and procedures complied with FCOI requirements for completing required FCOI disclosure reports and training.³⁰

²⁷ Some of the College’s NIH awards had more than one budget period.

²⁸ We selected two budget periods (years 16 and 17) for one of the five awards.

²⁹ We judgmentally selected 5 of 24 awards based on our analysis of detailed award transaction lists. Specifically, we selected 30 travel transactions, 30 salary transactions, and 32 cost transfer transactions based on our risk assessment and the knowledge we gained from similar audits at other colleges and universities. Generally, we consider these types of transactions as potentially high-risk charges to Federal awards.

³⁰ We judgmentally selected from NIH grant progress reports, 30 College employees and 5 subrecipient employees to test whether the College’s policies and procedures ensured that it complied with FCOI requirements for monitoring employees’ completion of required FCOI disclosure forms and FCOI training. We selected all 27 personnel that were assigned to the 5 awards included in the scope of our audit and 3 personnel from another NIH award. We judgmentally selected an additional 5 personnel assigned to 2 NIH subawards.

We limited our internal control review to obtaining an understanding of the College's policies and procedures for monitoring award expenditures and FCOI.

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, Appendix B contains Federal regulations and NIH award requirements, and Appendix C contains excerpts of the College's policies.

FINDINGS

The College did not always manage NIH awards in accordance with Federal and award requirements. Specifically, we found that before July 2019 the College used budget estimates instead of actual activity to claim \$7.5 million in salaries, fringe benefits, and indirect costs. We also found that after July 2019, the College created time and effort certification reports that contained illegible signatures or were not dated.³¹

In addition, we found that the College incorrectly charged \$73,515 to its NIH awards. Specifically, the College:

- charged \$44,763 in salary, fringe benefits, and related indirect costs that exceeded the NIH salary cap for calendar years 2017, 2018, and 2019;
- charged \$24,818 for a Principal Investigator's (PI) salary increase plus related fringe benefits and indirect costs that were contingent on the PI's retaining his external funding at his new pay level;

³¹ The College's Aug. 4, 2022, *Time and Effort Certification Policy* requires that all faculty and staff prepare a quarterly, written certification of time and effort. The effort certification form the College uses requires employees to certify the accuracy of the percentage of time (i.e., effort) charged to sponsored projects. According to College policy, the effort certification should be a reasonable estimate of how time was spent and accounts for 100 percent of all effort for which the College compensates the individual, including the time relating to non-sponsored activities such as teaching, grant writing, committee participation, administrative duties, department or other chairmanships, or other administrative responsibilities. College policy states that time and effort percentages are based on total effort, not hours.

College policy also requires that time and effort certification reports be signed by the employee. In cases where the employee is on approved leave for more time than the window for a PI to certify their report, the PI may sign and confirm that all activities (sponsored and non-sponsored) are reported correctly and that the distribution of effort shown on the certification report reasonably reflects the percentage of total effort that was spent on each activity.

- transferred to an NIH award the cost of supplies and related indirect costs totaling \$3,060 that did not meet Federal requirements; and
- charged \$874 in travel and related indirect costs that were unallowable or were not documented.

The College's system and procedures for accounting for personal services costs did not meet Federal requirements because it did not produce records that reasonably reflected the actual activity for which employees were compensated.³² The College did not have policies or procedures in place that ensured effort reports accurately reflected the work performed.

The College charged unallowable costs to NIH awards because it did not have systems or procedures in place to ensure that salaries did not exceed the NIH salary cap and were not paid based on a contingency of maintaining external funding. In addition, the College did not have systems or procedures in place to ensure that cost transfers and travel costs were documented and allowable.

Regarding our second objective, the College did not adequately monitor key individuals' records to ensure that those individuals met FCOI requirements for training and FCOI disclosures. Specifically, the College could not verify that 7 of 14 key individuals assigned to NIH awards completed required FCOI training and that 9 of the 14 key individuals completed required FCOI Disclosure Forms.^{33 34 35}

These conditions occurred because the College did not have adequate controls to ensure that key individuals assigned to NIH awards completed FCOI training every 4 years and filled out annual disclosure forms, as required by Federal regulations and College policy.

As a result, the College could not ensure that its NIH-funded research was free from bias by any conflicting financial interest and that key individuals understood their responsibilities of conducting NIH-funded research that was free from any FCOI.

³² 45 CFR §§ 75.430 (i) Standards for documentation of personnel expenses. (1) Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed.

³³ We used the College's FCOI policy in defining key individuals as those "who are significant participants in the project, i.e., those who will be decision makers or [are] responsible for the design, conduct and/or reporting of the funded research, including the principal investigator, co-investigators, sub-investigators, collaborators, and consultants."

³⁴ The College's FCOI policy states, in part, that investigators shall be required to complete training on the College's conflict of interest policy and the investigator's responsibilities regarding disclosure of Significant Financial Interests at least every four years and immediately when certain other conditions apply. *New York Medical College Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment*, dated May 31, 2012.

³⁵ 2019 NIHGPS, 4.1.10 "Financial Conflict of Interest."

THE COLLEGE CLAIMED SALARY AND RELATED COSTS USING BUDGET ESTIMATES

The College used budget estimates to claim \$7,469,306 in salary and wages, fringe benefits, and related indirect costs. Specifically, the College's records did not reflect the actual activity for which employees were compensated, including both federally assisted and all other activities for which employees were compensated. The College also did not document that it performed after-the-fact reviews of its initial budget estimates to ensure that amounts charged to its NIH awards were accurate, allowable, and properly allocated. Before July 2019, the College relied on budget estimates because it did not have an effort reporting process in place to produce records that reasonably reflected the actual activity for which an employee was compensated.³⁶

College officials said that starting in July 2019, it required all employees to account for their time by using quarterly effort reports. We tested both effort reporting processes by reviewing a judgmental sample of salary transactions that had been charged to NIH awards before and after July 2019.

Federal Requirements

Budget estimates alone do not qualify as support for charges to Federal awards but may be used for interim accounting purposes, provided that the system for establishing the estimates produces reasonable approximations of the activity performed, significant changes in the corresponding work activity are identified and entered into the records in a timely manner, and the system of internal controls includes processes to review after-the-fact interim charges made to Federal awards based on budget estimates. All necessary adjustments must be made such that the final amount charged to the Federal award is accurate, allowable, and properly allocated (45 CFR §§ 75.430(I)(1)(viii)(A), (B), and (C)).

Pre-July 2019 Effort Reporting Process

During our audit, we conducted interviews with management, as well as selected a judgmental sample to test the internal control issues we identified. As a result of these interviews and our testing, we concluded that the errors we identified were systemic and that the College claimed

³⁶ Before Aug. 4, 2022, the College had a policy document entitled, *Guidelines For Time And Effort Certification* that established guidelines for implementing time and effort certification. These guidelines, dated July 15, 2003, required the completion of Time and Effort Certification reports semi-annually. College officials said that beginning in 2015, they implemented a new accounting system using Electronic Personal Action Forms (EPAF) as time and effort certification reports. EPAF records identified an employee's gross annual salary and level of effort, expressed as a percent of the employee's time. The College preapproved the effort percentages that would be charged to various activities, including work on Federal awards. Because the EPAF is not a report of actual effort, the College could not use it to accurately record work performed or as the basis for allocating salaries and wages to NIH awards and other activities for which an individual was compensated. College officials said that in July 2019, they created a new time and effort reporting system that required time and effort certification reports to be signed on a quarterly basis and that in August 2022, they formally approved and updated the time and effort policy document to reflect these changes. The August 2022 policy document replaced the 2003 policy document.

\$7,469,306 in NIH salary and wage costs and related fringe benefits and indirect costs based on estimates rather than actual costs. Our review of 13 salary transactions totaling \$20,570 that were made between October 22, 2017, and June 16, 2019, were based on budgeted amounts and were not updated to reflect actual work performed.³⁷

Under the College's payroll system, when a professional employee was initially onboarded, their profile was set up for an annual salary paid biweekly and consisting of 70 hours. For hourly employees, their profile was set up using an hourly wage rate.

When the College applied for an award, it submitted a budget that included salaries and wages and related costs based on an anticipated level of effort expressed as a percentage that would be charged to the award. For example, the College would propose 3.6 calendar months of effort that would be devoted to the award period. For payroll purposes, these 3.6 calendar months would be converted to 30 percent effort ($3.6 \div 12 = .30$, or 30 percent).

Effort percentages were determined between the PI, department chair, and the correlating dean. According to College officials, the salary percentage for Federal awards was based on the allowable effort needed to complete the aims of the award.

Once the College received the award and approved percentages, the payroll system was updated, and the percentage was used to allocate a portion of the individual's salary to the award. However, the College did not provide documentation to show that it performed required periodic reviews of employee effort and any related adjustments to the percentage used to allocate salaries. According to College officials, they did not have a system before July 2019 that met Federal requirements, including periodic after-the-fact reviews of effort and any related adjustments to the amount charged to awards.

As a result of systemic issues with the College's effort reporting system before July 2019, salary and wages, fringe benefits, and related indirect costs totaling \$7,469,306 were at risk of not being expended for the purposes described in the College's NIH awards during the period October 1, 2017, through June 30, 2019.³⁸

³⁷ These 13 salary transactions are related to 7 individuals whose salary or wages were charged to 2 NIH awards. The 13 transactions covered 4 pay dates, from Oct. 22, 2017, through June 16, 2019. The 13 pre-July 2019 salary transactions were based on information contained in the employee's personnel salary file and the employee's EAPF and not a report of actual effort. The College preapproved the effort percentages that would be charged to various activities, including work on Federal awards.

³⁸ During our audit period, the College recorded in its accounting records salaries and wages and related fringe benefits and indirect costs totaling \$8,715,088. Of the \$8,715,088, \$7,538,888 was recorded for the period Oct. 1, 2017, to June 30, 2019, and the remaining \$1,176,200 was recorded for the period July 1, 2019, to Sept. 30, 2019. Of the \$7,538,888, we questioned \$69,582 in the findings below for two PI's salaries that exceeded the NIH salary cap and one PI's salary increase that was based on a contingency. This left \$7,469,306 in salaries, fringe, and related indirect costs that were charged to NIH awards before July 1, 2019, when the College did not have an effort reporting system that met Federal requirements.

Post-July 2019 Effort Reporting Process

The College recognized that its effort reporting process before July 2019 did not meet Federal requirements. In July 2019, College officials said that they created a new time and effort reporting system that required time and effort certification reports to be signed on a quarterly basis. In August 2022, after our audit started, the College instituted a formal effort reporting policy document to reflect the July 2019 changes to the system.³⁹ The policy requires that time and effort certification reports be signed on a quarterly basis by the employee's supervisor, or, in the case of an NIH award, the PI.

As part of our audit, we tested 17 salary transactions totaling \$23,606 that occurred between July 1, 2019, and September 30, 2019, to determine whether the current effort reporting process operates as intended. The College provided a certified quarterly effort report for each salary transaction, and we did not identify any errors related to the 17 transactions reviewed. However, we did identify issues that would not allow us or management to readily determine who signed some effort reports and when the effort reports were signed.

We also reviewed 15 time and effort certification reports under the College's effort reporting process that it initiated after July 2019 to determine if they were completed timely. We found the following:

- five were signed and dated by a PI;
- five were signed and dated, but the signature was illegible;⁴⁰ and
- five were signed but not dated.

Of the 10 effort reports that were signed and dated, the elapsed time from the end of the certification quarter until the date the effort report was signed ranged between 2 to 3 months, with an average of almost 2.5 months.

HHS regulation at 45 CFR § 75.430(i)(1)(i) requires records to be supported by a system of internal control that provides reasonable assurance that the charges are accurate, allowable, and properly allocated. The College's effort reporting policy does not specify a time frame in which effort reports should be signed and does not require that the employee's supervisor document their review by signing and dating the effort report. The absence of such requirements [or] internal controls could result in errors going undetected.

³⁹ The College's *Time and Effort Certification Policy*, dated Aug. 4, 2022.

⁴⁰ The College's time and effort certification reports did not contain the typed name of the individual who signed the report.

THE COLLEGE CLAIMED UNALLOWABLE NIH AWARD COSTS

The College claimed \$73,515 for costs that were unallowable. These unallowable costs included: (1) salaries and related fringe benefits and indirect costs that exceeded the NIH salary cap, (2) salaries and related fringe benefits and indirect costs that were contingent on a PI's receiving an NIH award, (3) cost transfers that did not meet Federal requirements, and (4) travel costs that were undocumented or were unallowable.

Salary Costs That Exceeded NIH's Salary Cap

We identified two instances totaling \$44,763 in which the College charged unallowable salaries, fringe benefits, and related indirect costs. These costs were unallowable because the PIs' salaries exceeded the NIH salary cap during the audit period.

Since 1990, Congress has mandated a limitation on direct salaries under NIH grants and cooperative agreements. The mandate appears in the annual appropriation act that provides authority for NIH to incur obligations for a given FY. NIH publishes annual guidance on the amount that an individual's annual salary may not exceed. This guidance is in the form of NIH's *Guidance on Salary Limitation for Grants and Cooperative Agreements* (NOT-ODs)⁴¹.

From our judgmental sample of 30 salary transactions, we identified 2 PIs whose salaries exceeded the NIH salary cap.

The first PI's salary exceeded the salary cap for several pay periods during 2017, 2018, and 2019 as shown in Table 1. Our calculation shows the College inappropriately charged \$32,871 in salaries, fringe benefits, and indirect costs to an NIH award.⁴²

⁴¹ During our audit period, NIH issued 3 NOT-ODs regarding the salary cap for NIH awards (NOT-OD-17-087, NOT-OD-18-137, and NOT-OD-19-099). For FY 2017, the salary cap was \$187,000. For FY 2018, the salary cap was \$189,600. For FY 2019, the salary cap was \$192,300.

⁴² The \$32,871 consisted of \$16,905 in salaries, \$3,139 in fringe benefits, and \$12,827 in indirect costs.

Table 1: OIG Calculation of Salary Cap Excess for PI #1

A: Year	B: Maximum Amount Chargeable Based on the NIH Salary Cap by Pay Period ⁴³	C: Gross Salary Charged to Award per Pay Period ⁴⁴	D: Percent Effort Charged to Award	E: Number of Pay Periods Charged When Salary Exceeded Cap	F: Salary Charged to Award Over the Cap (Columns (C - B) * E)	G: Fringe Benefits Charged to Award	H: Indirect Costs Charged to Award	I: Total Salary and Related Costs Over NIH Salary Cap
2017	\$4,979	\$5,484	69.22%	7	\$3,536	\$570	\$2,627	\$6,733
2018	\$5,048	\$5,484	69.22%	8	\$3,487	\$590	\$2,609	\$6,686
2018	\$5,326	\$5,557	73.04%	1	\$231	\$139	\$236	\$606
2018	\$5,252	\$5,557	72.02%	17	\$5,194	\$969	\$3,945	\$10,108
2019	\$5,327	\$5,557	72.02%	13	\$3,000	\$583	\$2,293	\$5,876
2019	\$5,327	\$5,569	72.02%	6	\$1,457	\$288	\$1,117	\$2,862
Total					\$16,905	\$3,139	\$12,827	\$32,871

College officials said that from September 2017 to early 2018, many discussions took place regarding salary adjustments for the PI. In May 2018, the College made changes to the PI's salary that were retroactive to 2017. These retroactive salary changes caused the PI's total salary to exceed the NIH Salary cap. College officials said that they should have made an adjustment to reflect the PI's new effort distribution based on the salary cap.

Table 2 below shows the second PI's salary, fringe benefits, and related indirect costs totaling \$11,892 was inappropriately charged to NIH award R56HL139561 because it exceeded the NIH salary cap.⁴⁵

In the July 2018 budget application for this award, the PI requested 3.6 calendar months, or 30 percent of effort of the NIH cap amount. The PI's salary was \$231,030 for 2018 and 2019. To account for the excess of salary over the cap, the College used a 21 percent effort rate to allocate the PI's salary to the award instead of the 30 percent rate, creating the overpayment (see Table 2).

⁴³ Amount that should have been charged to the award under the NIH salary cap. This amount is calculated as follows: annual salary rate ÷ 26 pay periods × percent effort charged to award (found here in column D).

⁴⁴ Does not include salary paid to the employee contingent on receiving NIH award funds. (See the "Contingent Salary Increase" section of this report).

⁴⁵ The \$11,892 in salaries, fringe benefits, and indirect costs charged to the NIH award over the cap consisted of \$6,098 in salaries, \$1,154 in fringe benefits, and \$4,640 in indirect costs.

Table 2: OIG Calculation of Salary Cap Excess for PI #2

A: Year	B: Maximum Amount Chargeable Based on the NIH Salary Cap by Pay Period ⁴⁶	C: Gross Salary Charged to Award per Pay Period ⁴⁷	D: Percent Effort Charged to Award	E: Number of Pay Periods Charged	F: Salary Charged to Award Over the Cap (Columns (C - B) * E)	G: Fringe Benefits Charged to Award	H: Indirect Costs Charged to Award	I: Total Salary and Related Costs Over NIH Salary Cap
2018	\$306	\$373	4.20%	1	\$67	\$12	\$50	\$ 129
2018	\$1,531	\$1,866	21.00%	4	\$1,339	\$243	\$1,012	\$ 2,594
2019	\$1,553	\$1,866	21.00%	15	\$4,692	\$899	\$3,578	\$ 9,169
Total					\$6,098	\$1,154	\$4,640	\$11,892

The College said that it believed charging the PI's salary at the 21 percent effort rate would keep the PI's salary under the NIH cap. However, the College may not have realized that it could not stay under the salary cap by arbitrarily adjusting the PI's effort percentage.

Contingent Salary Increase

In addition to exceeding the salary cap, one of the two PIs received a salary increase plus related fringe benefits and indirect costs totaling \$24,818 that was contingent on his maintaining external funding from NIH.⁴⁸ College officials informed the PI in a formal letter dated April 19, 2018, that "...Should your external funding not continue at least at this new level, your annualized compensation will be reduced." According to College officials, the PI was expected to keep the NIH award to continue receiving his pay increase.

Compensation costs must be reasonable, conform to the established policy of the organization, be consistently applied regardless of the source of the funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project.⁴⁹

⁴⁶ Amount that should have been charged to the award under the NIH salary cap. This amount is calculated as follows: annual salary ÷ 26 pay periods × percent effort charged to award (found here in column D).

⁴⁷ Does not include salary paid to the employee contingent on receiving NIH award funds. See the "Contingent Salary Increase" section of this report.

⁴⁸ The \$24,818 consists of \$12,587 in salary, \$2,546 fringe benefits, and \$9,685 in indirect costs.

⁴⁹ NIHGPS 7.9.1, "Salaries and Wages," Oct. 2017, Oct. 2018, and Dec. 2019.

For 7 pay periods in 2017, 26 pay periods in 2018, and 19 pay periods in 2019, the College charged salaries totaling \$287,930 to the PI's NIH award. For this same period, the College should have charged \$258,438.⁵⁰ As such, we determined that the \$29,492 difference—which consists of \$16,905 (Table 1) that was over the NIH salary cap and \$12,587 (footnote 45) that was based on a contingent pay raise the employee received—is unallowable.

College officials stated that after the NIH award expired on September 21, 2021, the PI's salary was not reduced, thus showing that his salary increase in 2018 was not contingent on maintaining external funding. Specifically, they stated that in April 2022, the PI's entire salary was charged to non-Federal funding sources to retroactively be effective September 21, 2021, when the PI's external funding expired. According to College officials, there was no contingency because (1) the PI's full salary amount was charged to the College's non-Federal funds when his Federal award ended in September 2021 and (2) the PI's full salary was never reduced.

Our finding captures the portion (\$12,587) of the PI's salary increase that was charged to the PI's NIH award during our audit period and was based on the contingency that the PI would maintain newly received external funding. Therefore, the steps the College took 3 years after the end of our audit period did not negate our finding that \$24,818 of the PI's salary increase plus related fringe benefits and indirect costs were not reasonable and were not consistently applied regardless of the source of the funds.

Cost Transfers

The College inappropriately transferred \$3,060, which included \$1,866 of supply costs and \$1,194 of related indirect costs, from one NIH award to another NIH award.

The NIHGPS provides that cost transfers to NIH awards that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification by a recipient official that the new charge is correct. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.⁵¹

During our audit, we reviewed 32 cost transfers totaling \$68,127. Six of those, totaling \$1,866, did not meet Federal requirements. Those 6 transfers all involved charges related to a single PI's NIH award. The College had transferred supply costs from the PI's primary NIH award to an NIH subaward the PI received from another University. The PI had \$1,866 that was unspent on

⁵⁰ We calculated the \$258,438 by subtracting the amount that the College should have allocated to the award each pay period based on the salary cap and the amount that the College should have allocated to the award each pay period without the PI receiving a pay increase that was contingent on the receipt of an NIH award for the number of periods shown in Table 1.

⁵¹ 2019 NIHGPS, 7.5, *Cost Transfers, Overruns, and Accelerated and Delayed Expenditures*.

the NIH subaward. According to the documentation the College provided, the subaward was ending and the College asked the PI if it was acceptable to transfer costs to the subaward. Rather than returning those funds to the University, the College transferred the \$1,866 of lab supply costs from the PI's primary NIH award to the subaward. The College's justification for the transfer was that the items "are all used for the experiments related to the [subgrant] project."

The College did not document that having unspent funds available from a PI's award was a reasonable basis for transferring costs to this same PI's second award nor did it provide documentation that showed that these cost transfers were needed to correct a bookkeeping error.

As a result, the College created an overpayment of \$3,060.

The College Claimed Some Travel Costs That Were Unallowable or Undocumented

The College claimed \$874 in travel and related indirect costs that were unallowable or undocumented. Specifically, the College claimed the following:

- \$386 for unallowable travel insurance, airline seat selection fees, and the cost of an alcoholic beverage that was included with a meal charge;
- \$147 for airfare, hotel, taxi, and parking costs that were not supported by documentation, such as receipts and invoices or other documentation that showed that the travel charges were related to the NIH award charged or were otherwise reasonable and allocable, and
- \$341 in associated indirect costs related to the unallowable travel costs.⁵²

Federal Requirements

The NIHGPS allows grantees to use their own travel policies if the policies are consistently applied regardless of the source of funds. The NIHGPS also provides awardees guidance on the allowability of costs and guidance on unallowable costs, such as alcohol charges. According to the NIHGPS, costs are allowable as long as they are allocable to an award based on the benefit received.⁵³

⁵² This amount was composed of \$247 of indirect costs attributable to \$386 in unallowable travel charges and \$94 of indirect costs attributable to \$147 in unsupported travel charges.

⁵³ 2019 NIHGPS, 7.9.1, "Allowable Costs."

Unallowable Travel Costs

We judgmentally selected for review 30 travel transactions totaling \$31,205. We found that 24 transactions totaling \$30,819 were allowable and six totaling \$386 were unallowable. All but one of those six transactions included costs for travel upgrades, such as seat selection fees; items classified as “extras;” and costs described on the traveler’s reimbursement voucher as “travel insurance or trip protection.” The College’s travel policy states that travel upgrades, including extra space, are non-reimbursable.⁵⁴ Regarding trip protection plans, College officials said that they reimburse for trip protection plans that they consider to be reasonable and necessary due to the trips’ circumstances, such as possible weather delays. However, the College did not provide any documentation to show that the travel upgrades and trip protection costs were reasonable and necessary due to the trips’ circumstances.

One sample item included reimbursement for the purchase of an alcoholic beverage. The College’s travel reimbursement policy prohibits the reimbursement for alcohol.

Unsupported Travel Costs

The College did not have documentation that supported \$147 in travel costs for 5 of the 30 sample items we examined.⁵⁵ For example, the College could not provide receipts or other appropriate documentation to support the costs claimed for airfare, taxis, parking, and tolls. According to the College’s travel policy, reimbursement requests must be submitted with receipts.

Policies and Procedures Were Not Followed or Were Lacking In Some Instances to Ensure That Costs Were Allowable

The College did not have policies and procedures to prevent the types of deficiencies we identified during our audit and in some instances, the College did not follow its policies and procedures. Specifically, we found that the College did not have a policy or procedure in place that would assist the College in managing salaries so that these amounts are at or under the NIH salary cap. Regarding the contingent salary increase, the College did not have a policy or procedure in place to ensure that compensation costs were consistently applied regardless of the source of the funds. The College also did not have policies and procedures that required cost transfers to meet Federal requirements. Finally, the College had travel policies and procedures in place for travel costs charged to NIH awards, but those policies and procedures were not always followed.

⁵⁴ The College’s travel and reimbursement policy states that non-reimbursable expenses include, travel upgrades, such as air, hotel, and car rental. Per policy, the College will not reimburse for seat upgrades (the College’s “Travel and Reimbursement Policy, Section IV, Policy Management and Responsibilities, General, Transportation, Air Travel”).

⁵⁵ Indirect costs related to the \$147 in unsupported travel costs were \$94.

THE COLLEGE DID NOT ALWAYS MEET CERTAIN FINANCIAL CONFLICT OF INTEREST REQUIREMENTS

The College did not always meet certain FCOI requirements. Specifically, the College could not verify that 7 of 14 key individuals assigned to NIH awards completed required FCOI training and that 9 of the 14 key individuals completed required FCOI Disclosure Forms (see footnote 33 for a description of key individuals). As a result, the College could not ensure that its NIH-funded research was free from any conflicting financial interest and that key individuals understood their responsibilities of conducting NIH-funded research that was free from any FCOI.

FCOI 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). See Appendix B for additional information regarding FCOI disclosure. Under certain circumstances, investigators and subrecipient investigators are required to complete training before starting NIH-funded research and then at least every four years.⁵⁶

We reviewed training completion certificates and FCOI disclosure forms for 35 individuals and determined that 14 were key individuals who were required to complete FCOI training and FCOI disclosure forms. The College verified that two of the key individuals completed the FCOI training and disclosure forms. However, it could not verify the following:

- 7 of the 14 key individuals completed the required FCOI training and
- 9 of the 14 key individuals completed the required FCOI disclosure forms.⁵⁷

These conditions occurred because the College did not have adequate controls to ensure that key individuals assigned to NIH awards completed FCOI training every 4 years and disclosure forms annually as required by Federal regulations and College policy.

During our audit period, the College relied on a combination of partial and fully automated systems to determine who had submitted required FCOI disclosure forms and who had completed required FCOI training. The system that the College used to track training completion was partially automated while the system it used to track completion of disclosure forms was fully automated. According to College officials, this “hybrid” system had the potential for human error. For example, the system called for the PI or department administrator to notify the College’s Office of Research Administration (ORA) of all departures and new hires. However, the PI or the department administrator did not always notify ORA,

⁵⁶ 2019 NIHGPS, 4.1.10 “Financial Conflict of Interest.”

⁵⁷ Of the 14 individuals, 6 were included in both the count of 7 individuals for whom FCOI training could not be verified and in the count of 9 individuals for whom FCOI disclosure forms were not completed.

which allowed some people who were required to complete FCOI disclosure forms or complete FCOI training to “slip through the cracks.” College officials said that they were taking steps to create a more comprehensive automated platform that was less subject to human error.

Absent adequate monitoring of its FCOI disclosure form and training completion processes, the College could not ensure that its NIH-funded research was free from bias by any conflicting financial interest and the College could not ensure that key individuals understood their responsibilities of conducting NIH-funded research that was free from any FCOI.

RECOMMENDATIONS

We recommend that New York Medical College take the following steps:

- work with NIH to determine the allowability of \$7,469,306 in salary and wages, fringe benefits, and related indirect costs that the College charged to its NIH awards during our audit period and refund any identified overpayments;
- refund \$73,515 in unallowable salary costs, cost transfers, and travel costs; and
- strengthen its internal controls by:
 - developing a policy or procedure for monitoring salaries so that they are at or under the NIH salary cap;
 - developing a policy or procedure that requires compensation costs to be reasonable, conform to established College policy, and be consistently applied regardless of the source of the funds and that reasonably reflects the percentage of time actually devoted to its NIH-funded projects;
 - working with NIH to quantify and refund any additional salary increases charged to NIH awards that were not reasonable, did not conform to established College policy, and were not consistently applied regardless of the source of funds;
 - completing the timely certification of employee time and effort reports to provide reasonable assurance that the charges are accurate, allowable, and properly allocated;
 - establishing time requirements for employees to sign and supervisors to review effort certification forms;
 - developing a cost transfer policy that includes the documentation requirements contained in NIH GPS 7.5;

- providing employees training on the specific types of travel expenses that the College considers non-reimbursable, such as alcohol and airline seat selection fees and training on the documentation needed to support travel costs; and
- monitoring key individuals' completion of annual FCOI disclosure forms and completion of required FCOI training.

NEW YORK MEDICAL COLLEGE COMMENTS AND OIG RESPONSE

In written comments on our draft report, the College generally disagreed with our three findings, but it agreed with the majority of our ten recommendations and described actions it had taken or planned to take to address them.

With its comments, the College provided additional documentation supporting \$113 in previously disallowed direct travel costs (\$69) and related indirect costs (\$44). Accordingly, we reduced our second finding and recommendation from \$73,628 to \$73,515. We also revised certain language in our third finding to clarify that the College had FCOI policies during our audit period but did not have adequate related internal controls to ensure compliance. We made no other changes.

Additionally, the College asserted that “The original [OIG] Senior Auditor notified the College that he had completed his audit work and was working to complete the written report when he retired in December 2021. Following the appointment of a new primary auditor, the audit was not immediately finalized, but instead the original scope of the audit was significantly expanded, without clear explanation, and the audit continued for almost two additional years.” We acknowledge that during the audit we experienced key staff changes due to retirements. While these staff changes affected our audit timelines, we refute the assertion that we expanded the original scope of the audit. The scope remained unchanged during the course of the audit.

Below is a summary of the College's comments on our findings and recommendations and our responses to those comments. The College's comments, redacted to exclude personally identifiable information and without exhibits, are included in their entirety as Appendix D.

THE COLLEGE CLAIMED SALARY AND RELATED COSTS USING BUDGET ESTIMATES

College Comments

The College did not agree with our finding that it claimed \$7,469,306 salary and related costs using budget estimates. However, it agreed with our recommendation to work with NIH to confirm the allowability of the salary, wages, fringe benefits, and related indirect costs charged to its NIH awards and take corrective action as appropriate.

The College did not agree with our finding that before July 2019, it did not have (1) an effort reporting process in place to produce records that reasonably reflected the actual activity for which an employee was compensated and (2) policies or procedures in place that ensured effort reports accurately reflected the work performed. College officials asserted that before July 2019, they used electronic personnel action forms (E-PAFs), research performance progress reports (RPPRs), ongoing monitoring of awards, and specific communications with PIs to ensure records reasonably reflected actual activity and accurately reflected the work performed. They also maintained that the combination of E-PAFs, RPPRs, and effort report certifications met Federal requirements before July 2019.

College officials disagreed that effort reports were not timely or were incomplete. However, they noted that they implemented a new time and effort reporting system in July 2019 and that the College published a new time and effort certification policy in 2022 to further strengthen the documentation of after-the-fact effort reporting. College officials agreed with our internal control recommendations regarding timely certification of employee time and effort reports and establishing time requirements for employees to sign and supervisors to review effort certification forms. They indicated that they provided additional training, improved effort certification forms, and implemented a revised time and effort certification policy on November 27, 2023, to address issues noted in the report.

OIG Response

We maintain that the College's effort reporting process in place before July 2019 did not produce records that reasonably reflected the actual activity for which an employee was compensated. We also maintain that the College's policies or procedures in place at that time did not ensure effort reports accurately reflected work performed.

Documentation provided by the College did not support its assertion that the combination of E-PAFs, RPPRs, and effort report certifications met Federal requirements before July 2019. Furthermore, the College provided no documentation to support that it used effort report certifications for salary costs before July 2019.

We believe the College's implementation of its new training, processes, effort reporting system, and effort certification policies should improve the assurance that labor charges are accurate, allowable, and properly allocated. However, our first finding and two related internal control recommendations remain unchanged.

THE COLLEGE CLAIMED UNALLOWABLE NIH AWARD COSTS

College Comments

The College did not agree that it claimed \$73,628 in unallowable NIH award costs.⁵⁸ It agreed that \$37,533 composed of salary, fringe benefits, and indirect costs (\$33,720), cost transfers (\$3,060), and travel costs (\$753) were improperly charged to an NIH award and indicated that it would coordinate with NIH to repay improperly charged expenses. However, the College maintained that the remaining \$36,095 of salaries, fringe benefits, and indirect costs exceeding the NIH cap (\$11,043), contingent salaries, fringe benefits, and indirect costs (\$24,818), and travel costs (\$234) were properly charged to an NIH award.

The College agreed with three of the five internal control recommendations related to our identification of unallowable NIH award costs. The College agreed to develop policies for monitoring salaries to ensure compliance with salary caps, to develop policies containing documentation requirements for cost transfers, and to provide training regarding travel expenses.

The College disagreed with the portion of our second finding related to \$24,818 that was charged contingent on the PI's retaining external funding, and it maintained that there was no non-compliance. Thus, the College disagreed with the recommendation to develop a policy or procedure requiring compensation costs to be consistently applied regardless of the source of funds. It also partially disagreed with the recommendation to quantify and refund any additional salary increases charged to NIH awards that were not consistently applied regardless of the source of funds.

OIG Response

Regarding our second finding and recommendation to refund \$73,628 in unallowable NIH award costs, the College agreed that it owed \$37,533, but it disagreed that it should return the remaining \$36,095. With its comments, the College provided additional documentation supporting \$113 in previously disallowed direct travel costs (\$69) and related indirect costs (\$44). Accordingly, we reduced our recommended refund amount from \$73,628 to \$73,515 but made no other changes.

The College's agreement and proposed actions to develop policies for monitoring salaries to ensure compliance with salary caps, to develop policies containing documentation requirements for cost transfers, and to provide training regarding travel expenses should mitigate the related portions of the second finding and address the three related internal control recommendations going forward.

⁵⁸ The \$73,628 in unallowable costs was composed of \$44,763 for salaries, fringe benefits, and indirect costs exceeding the NIH cap; \$24,818 for contingent salaries; \$3,060 for cost transfers; and \$987 in travel costs.

Regarding the College's assertion that there was no noncompliance related to the \$24,818 that we identified as salary paid contingent on the source of funds, we maintain that the College's support indicated otherwise, that its new time and effort policies did not address this issue, and that salary amounts paid under a statement requiring the researcher to maintain external funding were not allowable under the NIHGPS. Thus, our two related internal control recommendations remain unchanged.

Accordingly, other than the \$113 travel cost allowance based on additional support provided, our related findings and recommendations remain unchanged.

THE COLLEGE DID NOT ALWAYS MEET CERTAIN FINANCIAL CONFLICT OF INTEREST REQUIREMENTS

College Comments

The College disagreed that it did not always meet certain FCOI requirements. The College also disagreed that it did not have a written policy or procedure that directed key individuals assigned to NIH awards to complete FCOI training and disclosure forms. However, the College agreed that its internal controls in place before the audit did not adequately document completion of the training and disclosure requirements, and it agreed with the related internal control recommendation.

College officials said that in 2022, they implemented a new integrated FCOI software tracking and record retention platform to ensure full compliance with NIH FCOI expectations. College officials also said that while the new platform replaced the need for manual calculations, they implemented strict penalties to ensure compliance with the disclosure requirement, including a policy that failure to complete the annual disclosure could result in suspension without pay.

OIG Response

We agree that the College had a written policy that directed key individuals assigned to NIH awards to complete FCOI training and disclosure forms. Accordingly, we deleted the sentence in question from the report, "The College's monitoring process was inadequate because it did not include a written policy or procedure that directed key individuals assigned to NIH awards to complete FCOI training and disclosure forms as required by Federal regulations and the College policy."

In addition, we added language to clarify that this finding occurred because the College did not have adequate controls to ensure that key individuals assigned to NIH awards completed FCOI training every 4 years and filled out disclosure forms annually, as required by Federal regulations and College policy. The additional language reads, "These conditions occurred because the College did not have adequate controls to ensure that key individuals assigned to NIH awards completed FCOI training every 4 years and filled out annual disclosure forms, as required by Federal regulations and College policy."

Otherwise, our finding and the related internal control recommendation remain unchanged.

The use of the new platform and consistent implementation of any necessary penalties against key individuals who do not comply with training and disclosure requirements should preclude the recurrence of the College's noncompliance in this area.

We commend the College for taking corrective action, although we have not verified those actions.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 24 awards totaling \$17,172,846 that NIH awarded to the College and that were in effect from October 1, 2017, through September 30, 2019 (audit period). From those, we judgmentally selected five for review.⁵⁹

METHODOLOGY

To accomplish our objectives, we took the following steps:

- reviewed relevant Federal regulations, and NIH policies;
- met with personnel from the College's Compliance Department and personnel from its Office of Research Administration to gain an understanding of risks that it had identified relating to its NIH awards and determine if the College had completed any reviews or audits of its NIH awards;
- met with a PI for one of the College's NIH awards to gain an understanding of how the College monitors award expenditures;
- reviewed the College's policies and procedures for charging costs to Federal awards;
- judgmentally selected for review 92 transactions totaling \$143,508 that the College charged to 5 NIH awards for salary and wages (30 transactions totaling \$44,176); cost transfers (32 transactions totaling \$68,127); and travel costs (30 transactions totaling \$31,205) (see footnote 29);
- tested the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any NIH award limitations or exclusions;
- reviewed and held a discussion with College officials to gain an understanding of the College's written FCOI policies and procedures;
- reviewed the FCOI training records and FCOI disclosure forms associated with 35 judgmentally selected College employees and subrecipient employees (see footnote 30);
- discussed our findings with College officials on November 1, 2022;

⁵⁹ We selected two award periods (years 16 and 17) for one of the five awards.

- received additional information from College officials on November 16, 2022, in response to findings we discussed on November 1, 2022, and on July 6, 2023, we received additional information in response to a potential finding we discussed on June 28, 2023. We updated our report based on this additional information.

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 NIH AWARD REQUIREMENTS

FEDERAL REQUIREMENTS—ALLOWABILITY OF COSTS

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.

FEDERAL REQUIREMENTS—ALLOWABILITY OF COMPENSATION

The allowable compensation for certain employees is subject to a ceiling in accordance with statute (45 CFR § 75.430 (d), (2) - Compensation - personal services).

Standards for documentation of personnel expenses at 45 CFR §430(i)(1) states:

- (1) Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed. These records must:
 - (i) Be supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated;

(viii) Budget estimates (i.e., estimates determined before the services are performed) alone do not qualify as support for charges to Federal awards but may be used for interim accounting purposes, provided that:

(A) The system for establishing the estimates produces reasonable approximations of the activity actually performed;

(B) Significant changes in the corresponding work activity (as defined by the non-Federal entity's written policies) are identified and entered into the records in a timely manner. Short-term (such as one or two months) fluctuation between workload categories need not be considered as long as the distribution of salaries and wages is reasonable over the longer term; and,

(C) The non-Federal entity's system of internal controls includes processes to review after-the-fact interim charges made to a Federal award based on budget estimates. All necessary adjustment must be made such that the final amount charged to the Federal award is accurate, allowable, and properly allocated.

Base salary may not be increased as a result of replacing organizational salary funds with NIH award funds (NIHGPS 1, Glossary, 1.2, "Definition of Terms, Institutional Base Salary," 2019).

The NIHGPS states that compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time devoted to the NIH-funded project (NIHGPS, 7.9.1, "Selected Items of Cost, Salaries, and Wages," 2019; and 45 CFR §75.430(i)).

FEDERAL REQUIREMENTS—COST TRANSFERS

The NIHGPS provides that cost transfers to NIH awards by recipients must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable (NIHGPS, 7.5, "Cost Transfers, Overruns, and Accelerated and Delayed Expenditures," 2019).

FEDERAL REQUIREMENTS—TRAVEL EXPENSES

Travel expenses for employees of the recipient organization are governed by the recipient's travel policies, consistently applied regardless of the source of funds. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. Commercial recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including

the Maximum per diem and subsistence rates prescribed in those regulations. This information is available at <http://www.gsa.gov>. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs (NIHGPS 7.9.1).

FEDERAL REQUIREMENTS—FINANCIAL CONFLICT OF INTEREST

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.”⁶⁰ 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), on 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 § 75.112 state that:

- (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.

⁶⁰ 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)).

NIH Policies and Guidance Related to Financial Conflict of Interest

According to the 2019 NIHGPS, 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.⁶¹

⁶¹ Available online at <https://grants.nih.gov/grants/policy/coi/index.htm>. Accessed on Nov. 2, 2022. NIH has made several changes in its guidance on FCOIs since the end of our audit period.

APPENDIX C: COLLEGE POLICY EXCERPTS

Allowable Travel Costs

The College's policy states that it is the responsibility of the traveler and the College to ensure, among other things, that all expenses are actual, allowable, reasonable and necessary; travelers obtain appropriate approvals before incurring expenses; any exceptions to this policy are justified and documented; and accurate records are maintained, including departure and return times and mileage (the College's *Travel and Reimbursement Policy, Section IV, Policy Management and Responsibilities, General*).

The College's travel and reimbursement policy states that non-reimbursable expenses include, travel upgrades, such as air, hotel, and car rental. Per policy, the College will not reimburse for seat upgrades (the College's *Travel and Reimbursement Policy, Section IV, Policy Management and Responsibilities, General, Transportation, Air Travel*).

Federal regulations (and where sponsors so dictate) prohibit the reimbursement of alcoholic beverages with federal funds under any circumstances (the College's *Travel and Reimbursement Policy, Section IV, Policy Management and Responsibilities, Sponsored Programs*).

Financial Conflicts of Interest Disclosure and Training

The College's policies require that FCOI disclosures be: (1) made before the submission of an application to the sponsor for research and other sponsored projects, (2) updated annually for the duration of the research and other sponsored projects, and (3) updated within 30 days of acquiring any such new activity or interest (e.g., through gift, marriage inheritance). The investigator's disclosure forms must be submitted even if there is no interest, position, or rights to disclose.

Disclosures shall be required of all individuals who are significant participants in the project, i.e., those who will be decision makers or are responsible for the design, conduct and/or reporting of the funded research, including the PI, co-investigators, sub-investigators, collaborators, and consultants (New York Medical College, Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment, VII., B. Policy 2., Disclosure, May 31, 2012).

College policy requires that before engaging in research or any other academic activity for which extramural support is sought, investigators shall be required to complete training on the College's conflict of interest policy and the investigators' responsibilities regarding disclosure of significant financial interests at least every four years and immediately when any of the following apply:

- a. The College revises its policy or procedures on conflict of interest;
- b. An investigator is new to the College; or

- c. The College finds that an investigator is not in compliance with the College's policy (New York Medical College, Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment, VII., B. Policy 1. Training, May 31, 2012).

APPENDIX D: COLLEGE'S COMMENTS



TOURO UNIVERSITY
NEW YORK MEDICAL COLLEGE



Salomon Amar, DDS, PhD

Senior Vice President for Research Affairs

Chief Biomedical Research Officer

Touro University

Vice President for Research

Professor of Pharmacology, Microbiology and Immunology

New York Medical College

Vice Dean of Research

Professor of Dental Medicine

Touro College of Dental Medicine at New York Medical College

December 1, 2023

Lori S. Pilcher

Regional Inspector General for Audit Services, Region IV

Office of Inspector General

Department of Health and Human Services

61 Forsyth Street, SW Suite 3T41

Atlanta, GA 30303

RE: Report Number A-04-20-03583

Dear Ms. Pilcher:

New York Medical College (the College) appreciates the opportunity to provide this letter in response to the Office of Inspector General's draft report, *New York Medical College Claimed Unallowable Grants Costs and Did Not Meet Certain Financial Conflict of Interest Requirements*, dated October 25, 2023 ("Draft Report").

We recognize that your audit of New York Medical College was one of a series of audits of institutions of higher education that were recent grant recipients of the National Institutes of Health (NIH). We note that this audit presented several challenges for the College. The audit was commenced during the COVID pandemic in 2020 as a remote review, an unusual situation for both the College and the auditors. The original Senior Auditor notified the College that he had completed his audit work and was working to complete the written report when he retired in December 2021. Following the appointment of a new primary auditor, the audit was not immediately finalized, but instead the original scope of the audit was significantly expanded, without clear explanation, and the audit continued for almost two additional years.

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

Touro University System

NEW YORK OFFICE

320 West 31st Street

New York, NY 10010

T: 646.565.6000

salomon.amar2@touro.edu

New York Medical College

VALHALLA OFFICE

40 Sunshine Cottage Road

Valhalla, NY 10595

T: 914.594.4575

salomon_amar@nymc.edu

Please note that certain information in the attached exhibits is exempt from FOIA release due to the inclusion of confidential commercial information, as well as information that would invade personal privacy of College employees if released.

1. Finding 1: The College Claimed Salary and Related Costs Using Budget Estimates

[T]he College's records did not reflect the actual activity for which employees were compensated, including both federally assisted and all other activities for which employees were compensated. The College also did not document that it performed after-the-fact reviews of its initial budget estimates to ensure that amounts charged to its NIH awards were accurate, allowable, and properly allocated. Before July 2019, the College relied on budget estimates because it did not have an effort reporting process in place to produce records that reasonably reflected the actual activity for which an employee was compensated.

Pre-July 2019 Process

The College disagrees with the finding that before July 2019 “it did not have an effort reporting process in place to produce records that reasonably reflected the actual activity for which an employee was compensated” and the statement in the Draft Report that prior to July 2019, “[t]he College did not have policies or procedures in place that ensured effort reports accurately reflected the work performed.” Prior to July 2019, the College used electronic personnel action forms (E-PAFs), research performance progress reports (RPPRs), ongoing monitoring of grants, and specific communications with principal investigators (PIs) to ensure records reasonably reflected actual activity and accurately reflected the work performed.

The Draft Report states that “the review of 13 salary transactions totaling \$20,570 made between October 22, 2017 and June 16, 2019 were based on budgeted amounts and were not updated to reflect actual work performed.” The Draft Report also states that “[a]ccording to College officials, they did not have a system before July 2019 that met Federal requirements, including periodic after-the-fact reviews of effort and any related adjustments to the amount charged to awards.” These statements are inaccurate and appear to be due to a misunderstanding by the auditor and/or a miscommunication by College officials.

Federal regulations at 34 CFR § 75.430(i)(1)(viii) allow budget estimates to be used for interim accounting purposes provided that:

- (A) The system for establishing the estimates produces reasonable approximations of the activity actually performed;
- (B) Significant changes in the corresponding work activity ... are identified and entered into the records in a timely manner...;
- (C) The non-Federal entity's system of internal controls includes processes to review after-the-fact interim charges made to a Federal awards based on budget estimates. All necessary adjustment must be made such that the final amount charged to the Federal award is accurate, allowable, and properly allocated.

Prior to July 2019, when new personnel expenses were added to a grant, the PI submitted E-PAFs to the College grants administration and payroll departments based on reasonable approximations of the activity to be performed. *See, e.g.*, Exhibit 1 (initial E-PAF for P. Nisubmitted January 31, 2018, showing employee budgeted for 100% effort on NIH-funded grant effective January 8, 2018). After-the-fact charges were reviewed in connection with the annual RPPRs. *See, e.g.*, Exhibit 2 at 7 (RPPR identifying effort of 100% for five calendar months covering the period 8/1/2017-4/31/2018, which provides the after-the-fact validation of the E-PAF). Many times, updated E-PAFs indicated retroactivity of changes which provides further after-the-fact validation of prior budgeted amounts. *See, e.g.*, Exhibit 3 (E-PAF submitted on October 10, 2018 increasing a researcher's effort from 0% to 8.39% effort on a federal grant retroactive to July 15, 2018 and corresponding RPPR for the period 7/15/2018-6/30/2019 reporting the equivalent 1/12 effort).

The combination of E-PAFs, RPPRs, and effort report certifications met Federal requirements prior to July 2019. Charges to federal awards for salaries and wages were based on records that accurately reflected the work performed, "as supported by a system of internal controls which provide[d] reasonable assurance that the charges [were] accurate, allowable, and properly allocated. 34 CFR § 75.430(i)(1)(i). Accordingly, the College does not agree with the Draft Report's characterization that the effort reporting system in place prior to July 2019 had systemic issues or that \$7,469,306 of salary and wages, fringe benefits and indirect costs were at risk of not being expended for the purposes described in the College's NIH awards.

Post-July 2019 Process

The Draft Report identified concerns with 10 of the 15 time and effort certification reports reviewed that were initiated after July 2019. Five of the reports were signed and dated, but the signature was deemed illegible by the auditors. Five of the reviewed time and effort certification reports were signed but not dated. There is no federal requirement that time and effort certification reports be signed with a legible signature or that signatures be dated. Charges to federal awards for salaries and wages must be based on records that accurately reflected the work performed, as "supported by a system of internal controls which provides reasonable assurance that the charges are accurate, allowable, and properly allocated." 34 CFR § 75.430(i)(1)(i). The College's time and effort certification report collection process in effect during the audit period provided the reasonable assurance that the College understood who was signing reports and when those reports were signed.

The five time and effort certification reports deemed as illegible in the Draft Report were all signed by a single PI on March 10, 2020, right at the time the College, and most of the country, was shutting down for the COVID pandemic. *See Exhibit 4 (Illegible signature reports)*. The Restricted Funds department was scrambling to pick up records before the entire College went remote. The same day as the reports were signed, the College's Restricted Funds official exchanged an email with the PI's administrative assistant to arrange for a physical collection of the signed certification reports. *Exhibit 5*. The College had full knowledge of the identify of the report signer, and a sloppy signature by a PI did not negatively impact the accuracy of the report. The College notes that, in response to the Draft Report, the College has now added a typed name line on certification reports. *See Exhibit 6 (New report format)*.

The Draft Report also noted that, despite not being a specific federal requirement, five of the reviewed time and effort certification reports were not dated. While the signatures for all five reports were obtained in-person by the Director of Restricted Funds during the same hurried pandemic physical collection scramble in early March 2020, the College agrees dates are valuable information for audit purposes and has provided training to the Restricted Funds team on the importance of confirming that all submissions are dated and returning any missing dates to the PI for completion.

2. Finding 2: The College Claimed Unallowable NIH Award Costs

The Draft Report states that the College claimed a total of \$73,620 for costs that were unallowable. We have addressed these costs according category below.

a. Two instances totaling \$44,763 of salaries and related fringe benefits and indirect costs that exceeded the NIH salary cap

The College agrees that due to internal errors, \$32,871 of over-the-cap expenses (\$20,044 direct and \$12,827 indirect costs) were improperly charged to an NIH award as identified in Table 1 of the Draft Report. As discussed further in response to the Draft Report recommendations later in this response, the College has implemented a new procedure to ensure PIs with total compensation in excess of the salary cap are reviewed manually by senior members of the Grants Accounting team to ensure that all compensation charges allocated to federal grants fully comply with NIH requirements. The College will also coordinate with NIH to repay these \$32,871 of improperly charged expenses.

The College agrees there was a second instance of over-the-cap expenses improperly charged to an NIH award; however, the College asserts that the amount of the improper charge is \$849, not the \$11,892 cited in Table 2 of the Draft Report, due to a rounding error by the PI. The Draft Report applies a 21% effort rate. However, the PI attested to 25% effort (represented as 3.0 calendar months) on the RPPR report. See Exhibit 7. Applying the 25% effort rate, as attested to by the PI on the RPPR report, results in a corrected Table 2 of:

A: Year	B: Maximum Amount Chargeable Based on the NIH Salary Cap by Pay Period	C: Gross Salary charged to Award per pay period	D: Percent Effort Charged to Award	E: Number of Pay periods charged	F: Salary Charged to Award over the Cap (C-B)*E	G: Fringe Benefits Charged to Award	H: IDC	I: Total over cap
2018	\$364 ¹	\$373	5% ²	1	\$9	\$1.50	\$6.72	\$17.22
2018	\$1823	\$1866	25%	4	\$172	\$31	\$129.92	\$332.92
2019	\$1849	\$1866	25%	15	\$255	\$49	\$194.56	\$498.56
Total					\$436			\$848.7

¹The \$306 in the original Table 2 of the Draft Report was based on annual salary cap / 26 pay periods x percent effort charged to the grant (\$189,600 / 26 x 4.2%). Applying 25% effort with the same calculation results in the maximum amount chargeable of \$364 (\$189,600 / 26 x 5.0%).

²The 4.2% in the original Table 2 of the Draft Report was based on a pro-rated 21% effort across 2 out of 10 work days during the pay period (.21 x .2 = 4.2%). Applying 25% effort with the same proration results in 5% (.25 x .2 = 5%).

The College disputes the Draft Report's characterization on page 14 of the 21% as an arbitrary adjustment. To the contrary, the 21% adjustment was a deliberate, albeit incorrectly rounded, adjustment intended to comply with the NIH cap.

The 2018 Salary Cap totaled \$189,600. The PI reported 25% effort at that cap amount for a total of \$47,400 to be allocated to the grant ($\$189,600 \times 25\% = \$47,400$). To properly adjust the PI's salary of \$231,030 so that no more than \$47,400 was charged to NIH funds, the College needed to limit the charge of the PI's total salary to 20.52% ($\$47,400 / \$231,030 = .2052$) of the grant. College officials believe that when this 20.52% calculation was entered into a spreadsheet, the person doing the data entry failed to recognize that the spreadsheet automatically rounded the percentage to the closest number without decimals (21%), resulting in a minor overage. The 21% is a rounding error of 20.52%—not an arbitrary number as suggested in the Draft Report. The College has implemented additional reviews, including in the pre-award planning stage, to assist PIs in properly calculating applicable salary caps to identify and rectify any calculation errors before NIH grants are charged.

The College will coordinate with NIH to repay these \$848.70 of improperly charged expenses due to the clerical rounding error.

- b. One of the two PIs reviewed received a salary increase and related fringe benefits and indirect costs totaling \$24,818 that was contingent on his maintaining external funding from NIH.*

The Draft Report identifies concern with language in a PI's letter stating "Should your external funding not continue at least at this new level, your annualized compensation will be reduced" by labeling it proof of a contingency. The Draft Report incorrectly asserts the use of this language is in violation of NIHGPS 7.9.1, which states:

Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project.

The Draft Report accurately notes that the compensation of the PI in the audit was not reduced once the NIH funding ended but stubbornly continues to label this language as proof of a contingency. Contingent is defined as "occurring or existing only if (certain circumstances) are the case; dependent on."³ So, a compensation amount can't be "contingent" on a federal grant if the compensation amount continued to be paid for years after federal funding ceased. The fact that the College continued to pay the full compensation via non-federal sources after the NIH grant ended de facto demonstrates that the PI's specific compensation level was not contingent on the NIH funding.

The language of the compensation letter identified in the Draft Report ([s]hould your external funding not continue at least at this new level, your annualized compensation will be reduced) conveys to faculty members that productivity was one factor in a compensation decision. NIHGPS 7.9.1 does not prohibit a college from considering overall productivity as one of many factors in determining a faculty member's compensation, which is what New York Medical College does. For tenured faculty who are entitled

³ Oxford languages, Oxford University Press via Google.com.

under College policy to tenure of certain salary increases, the language conveys that the College considers the compensation outside the tenure salary guarantee and reserves the right to remove the increase in the future.

In accordance with NIHGPS 7.9.1, New York Medical College applies this language and approach consistently, regardless of the source of funds. *Compare* Exhibit 8 (Letter of NIH-funded PI identified in audit) *with* Exhibit 9 (Letter of researcher who received increase but has no federal funding). The language of both letters, to faculty with different funding sources, is consistent, which demonstrates the organization is consistently applying its policy regardless of the source of funds.

The Draft Report further states that \$12,587 of the salary was not reasonable compensation, but it provides no support for such a declaration. The annual salary of the federally funded PI as of September 1, 2017 was \$196,682, which was determined to be reasonable compensation by the College based on reviewing comparable compensation data. The Association of American Medical Colleges ("AAMC") provides compensation statistics for member institutions like New York Medical College. According to the AAMC, the 2016-2017 median compensation for Northeastern Region PhD Professors in departments of Pharmacology was \$185,000 and average compensation was \$195,300.⁴ Contrary to the assertion in the Draft Report, compensation that is consistent with labor market demands, as verified by comparisons to the median and average compensation rates of comparable professors at comparable institutions is reasonable compensation.

c. Cost transfers that did not meet Federal requirements.

The Draft Report asserts that \$1,866 of supply costs that were transferred from one NIH award to another NIH award were inappropriate because the transfer did not comply with 2019 NIHGPS 7.5.

NIHGPS 7.5 states:

Cost transfers to NIH grants by recipients, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the recipient, consortium participant, or contractor.

The College implements transfer of costs within 90 days of when the errors are discovered. The supporting documentation for the cited transfer included a certification of the correctness of the new charge by the PI, who certified the supplies were used on the work of the grant they were transferred to. However, the College acknowledges that the documentation did not fully explain how the error occurred. Accordingly, while the charge was appropriate for the grant⁵, the College concurs that the transfer did not meet all requirements of NIHGPS 7.5. As discussed further later in this response, the College has implemented a new process to ensure that all required documentation is maintained for any cost transfers.

⁴ Table 21 from the AAMC 2016-2017 compensation report is attached as exhibit 10.

⁵ The College provided a 2018 email from the PI certifying the CO2 was required for cells/tubule incubation and several reagent purchases were required for preparation of kidneys used in the research to check the expression of proteins in research animals on the grant ultimately charged.

d. Travel costs that were undocumented or were unallowable.

The Draft Report cites \$216 in unallowable or undocumented travel costs. The eight sample items noted as unallowable or undocumented travel costs were related to parking, taxis, and tolls. They were not related to airfare as the Draft Report states.

The College provided the auditors receipts documenting three of the eight items identified in the Draft Report.

- Receipts were provided for sample item 3 (\$24). The auditors acknowledged this will be adjusted in the final audit report in their most recent communication with the College.
- Receipts were provided for sample item 4 (\$5.76). The auditors acknowledged this will be adjusted in the final audit report in their most recent communication with the College.
- The College previously provided all receipts for sample item 8. This travel item had a total of \$81.06 in taxis fares (Uber) and all receipts were provided ($\$12.08 + \$10.00 + \$8.73 + \$11.11 + \$39.14 = \81.06). The Draft Report appears to reject the receipt for \$39.14, attached as exhibit 11, without explanation.

Accordingly, the College believes the report should be updated to remove these three charges totaling \$68.90, as well as related indirect costs, from the finding.

The College's travel policy, effective September 2000, did not require receipts for expenses less than \$25. See Exhibit 12 (September 2000 policy). This policy was in effect until it was replaced in December 2017. This 2017 travel policy required receipts for all expenses, regardless of amount, but authorized the Vice President (VP) for Financial Operations to approve deviations from the policy for good cause. See Exhibit 13 (December 2017 policy).

Three of the undocumented or unallowable charges in the Draft Report related to a PI who was frequently traveling for his research. This PI had consistently traveled to the same peer institution for several months for his research. The PI was unable to locate certain parking receipts, and these expenses were approved deviations by the VP for Financial Operations since they each was less than \$25, all were consistent with previous similar travel by this same PI, and one parking receipt for travel to this location was provided and maintained on file. These were sample items 2, 26 and 27; \$10, \$16 and \$48 (6 receipts of \$8 each⁶), respectively. The College therefore believes the Draft Report should be adjusted to remove these charges from unallowable or undocumented items since they were an approved deviation.

The College concurs with the auditor's assessment of the remaining two items noted as undocumented (samples 14 for \$31 and 28 for \$42). The College also concurs with the \$386 charges for travel insurance, airline seat selection fees, and an alcoholic beverage as being unallowable. The College believes these were isolated errors. Finance managers met with the individuals responsible for the review of the travel expense reimbursements (Restricted Funds department, Accounts Payable department, and Director of Purchasing) and reinforced the importance of a detailed and thorough review of each travel expense item to ensure full compliance with College policy. Additionally, the Controller's Office is preparing a more formal training on the Travel Expense Policy with the College community in January 2024.

⁶A seventh \$8 parking receipt had been submitted by the investigator in connection with the reimbursement and this charge not cited as a finding in the Draft Report.

3. Finding 3: The College did Not Always Meet Certain Financial Conflict of Interest Requirements

Page 8 of the Draft Report states “[t]he College’s [Financial Conflict of Interest (FCOI)] monitoring process was inadequate because it did not include a written policy or procedure that directed key individuals assigned to NIH awards to complete FCOI training and disclosure forms...” The College disagrees with this statement and notes that it is directly contradicted by footnote 33 of the Draft Report, which quotes sections of the 2012 policy documenting the requirement for key individuals to complete training and disclosure forms.

The College’s conflict of interest policy during the audit period was documented in the New York Medical College Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment dated May 31, 2012. That policy was amended by a uniform conflict of interest policy for the Touro College and University System dated December 22, 2020. That policy was further amended by a uniform conflict of interest policy for the Touro College and University System dated June 30, 2022, which is currently in effect⁷.

Under the College’s prior and current policies, PIs must complete training on the College’s conflict of interest policy before initially engaging in research, and thereafter at least every four years and immediately when certain other conditions apply. Under the College’s prior and current policies, key individuals involved in research must complete disclosures of conflicts of interest at least annually.

The College agrees that the internal controls in place prior to the audit failed to adequately document completion of the training and disclosure requirements, as evidenced by the College’s inability to produce 14 requested documents as part of the audit. The College previously managed its FCOI process through multiple spreadsheets, multiple reporting systems, and manual date calculations for each respondent. The Draft Report accurately describes the College’s root cause analysis related to use of this hybrid tracking system that left too much room for human error.

In response to this concern, in 2022 the College transitioned conflict of interest reporting and tracking to its Mentor software platform. The Mentor platform was previously, and continues to be, used for IRB study tracking and other Office of Research Administration (ORA) recordkeeping. Use of a unified system provides ORA consistent reporting prior to authorization of research activities. If a participant has not completed each of the required compliance training and disclosure, they cannot participate in the grant until completed. All participants on a grant are confirmed to have completed the required training and the disclosure survey via checking a tab in Mentor. Mentor provides each of the participant’s dates of completion and automatically calculates required renewal dates, replacing the prior need for manual calculations. See Exhibit 14 (Example screenshots from Mentor tracking system).

Disclosure completions in Mentor are automatically transferred to the College’s human resource and financial information system, Banner, several times a day. Banner automatically flags individuals who have not submitted or completed their annual FCOI disclosure. The College’s Human Resources (HR) staff

⁷ The College provided copies of all policies to the auditors. Consistent with NIH requirements, the current policy is publicly available on the College website at <https://www.nymc.edu/media/schools-and-colleges/nymc/pdf/policies/UniformConflictofInterestPolicyrevised06.24.2022Boardapproved6.30.22.pdf>

are then able to follow-up with these employees to ensure that the FCOI survey is completed in a timely manner. The College has implemented strict penalties to ensure compliance with the disclosure requirement. Failure to complete the annual disclosure results in suspension without pay. *See Exhibit 15 (Final warning notification sent to non-compliant employees in June 2023).*

The Mentor FCOI module has now optimized disclosures. Users indicate a reason for submission from the following options: (1) Annual disclosure per policy; (2) I am listed on a pending application or funded grant in the past year; (3) I am listed on an IRB application that is currently active or active in the past year; (4) I am listed on an IACUC application that is currently active or active in the past year; or (5) I participate in research. Users are able to check off all applicable responses, and the reason informs Mentor on automated routing of responses to the correct College offices for proper review. Once the reason for submission is complete, the disclosure form asks the user not only if he/she participates in research, but more specifically, whether he/she participates in NIH-sponsored research. If the user responds “yes” to participating in NIH-sponsored research, the questionnaire asks: (1) provide the grant number; (2) do you or anyone in your immediate family, have a financial interest related to the NIH grant or grants listed above; (3) nature and value of potential conflict of interest (i.e., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interest, reimbursed or sponsored travel, or other; (4) financial levels; and (5) a description of how the financial interest is related to the NIH-funded research. The FCOI questionnaire allows the College to obtain sufficient information so that it can create, when necessary, a conflict management plan.

If an investigator has no new conflicts to report in a disclosure, the Mentor system allows them to easily and quickly affirm the prior disclosure as still valid as of a new submission date⁸. The unified Mentor system now maintains all historical reporting for the record retention period eliminating the risk of lost or misfiled evidence of training and disclosure completion.

Mentor also has a repository of the completed conflict of interest training. *See Exhibit 14.* Training data is linked to each conflict of interest disclosure for review by HR and is also linked to each research protocol submitted to the various IRBs, the IACUC, and the IBC. These committees are thus able to document and ensure that all individuals engaged in research have the appropriate conflict of interest training (as well as other trainings appropriate to their specific research projects).

The significant investment of time and funding to implement and maintain the Mentor FCOI module will ensure that the College is able to document full compliance with College FCOI policy and NIH requirements.

4. Recommendation 1: Work with NIH to determine the allowability of \$7,469,306 in salary and wages, fringe benefits, and related indirect costs that the College charged to its NIH awards during our audit period and refund any identified overpayments.

The College agrees to work with NIH to confirm the allowability of the salary, wages, fringe benefits and related indirect costs charged to our NIH awards and take correction action as appropriate.

⁸ The previous non-Mentor system required all respondents to provide a complete disclosure every year, without providing easy reference or access to prior submissions. Frustration and annoyance by investigators created reluctance to timely compliance. The ease of the new system now facilitates compliance.

5. Recommendation 2: Refund \$73,628 in unallowable salary costs, cost transfers, and travel costs.

As explained above, the College disagrees that all \$73,628 are unallowable salary costs, cost transfers and travel costs. The College concurs that direct costs of \$20,561.50 in salary, \$1,866.00 in cost transfers and \$459 in travel costs did not fully meet requirements and agrees to work with NIH to refund \$22,886.50 of direct costs plus the associated indirect costs. As noted above, the College contends that the difference between these amounts are allowable salary costs and travel costs because the Draft Report applies an inaccurate effort rate to a salary cap calculation, a PI's salary increase complied with NIHGPS 7.9.1 and certain identified travel costs were compliant with both the NIH and the College's travel policies and requirements.

6. Recommendation 3: Strengthen internal controls through the following:

- a. Developing a policy or procedure for monitoring salaries so that they are at or under the NIH salary cap.*

The College agrees with this recommendation and has implemented a new salary cap administration policy and procedure to ensure that salaries charged to NIH grants comply with the NIH salary cap. See Exhibit 16 (New policy and procedure). The policy document provides a clear example calculation for the NYMC research community, and it ensures that salary cap limitations are identified at the pre-award stage and processed E-PAFs do not exceed the applicable cap. The College is preparing further training materials to be circulated to the research community in early 2024.

- b. Developing a policy or procedure that requires compensation costs to be reasonable, conform to established College policy, and be consistently applied regardless of the source of funds and that reasonably reflects the percentage of time actually devoted to its NIH-funded projects.*

The College agrees that compensation costs must be reasonable, conform to established College policy, be consistently applied regardless of source of funds, and reasonably reflect the percentage of time actually devoted to NIH-funded projects. As noted above, the College disagrees that the audit identified any examples of non-compliance. The single compensation increase identified as concerning in the Draft Report was not contingent upon continued NIH funding, was reasonable as judged by pay rate data from the labor market for comparable faculty, consistently applied the College's established communication policy regardless of the source of funds, and reasonably reflected the percentage of time actually devoted to the NIH-funded project. In 2022, the College implemented a new time and effort certification policy to strengthen the documentation of after the fact effort reporting. As a result of suggested process improvements in the Draft Report, the College issued a revised time and effort certification policy on November 27, 2023. See Exhibit 17.

- c. Working with NIH to quantify and refund any additional salary increases charged to NIH awards that were not reasonable, did not conform to established College policy, and were not consistently applied regardless of the source of funds.*

The College agrees to work with NIH to quantify and refund any additional salary increases charged to NIH awards that were not reasonable, did not conform to established College policy, and were not consistently applied regardless of the source of funds.

- d. Completing the timely certification of employee time and effort reports to provide reasonable assurance that the charges are accurate, allowable and properly allocated.*

The College agrees that certified employee time and effort reports must be timely completed to ensure charges are accurate, allowable and properly allocated. As the Draft Report recognizes, the College implemented a new time and effort reporting system in July 2019. In 2022, the College published a new time and effort certification policy to further strengthen the documentation of after the fact effort reporting. The College disagrees that illegible signatures or unrecorded dates on certain of the sampled reports, all collected at the very beginning of the COVID pandemic shutdown, impacts the timeliness of the certifications; however, the College has implemented improved processes as a result of the audit. The College's effort report now requests that certifiers both sign and print their name. The College agrees dates are valuable information for audit purposes and has provided training to the Restricted Funds team on the importance of confirming all submissions are dated and returning missing dates to the PI for completion.

- e. Establishing time requirements for employees to sign and supervisors to review effort certification forms.*

The College agrees that clear time requirements for return of certification forms, while not formally required by federal requirements, is a valuable practice to facilitate grant administration. The 2022 Time and Effort policy, previously provided to the auditors, stated that PIs were responsible for returning the certified reports to the Restricted Funds department within two weeks. See exhibit 18. As a result of suggested process improvements in the Draft Report, the College issued a revised time and effort certification policy on November 27, 2023. See exhibit 17. The 2023 policy requires certified effort reports to be returned to the Restricted Funds department within three weeks of being provided to the researcher. The new policy requires all faculty to certify their own effort reports and for the effort reports of all non-faculty to be certified, with a signature and date by a responsible supervisory official having firsthand knowledge of all the activities performed by the researcher. Additionally, PIs, must certify all effort reports.

- f. Developing a cost transfer policy that includes the documentation requirements contained in NIH GPS 7.5.*

The College implemented a new cost transfer policy in April 2023 (see Exhibit 19) that includes the documentation requirements of NIH GPS 7.5. A cost transfer form is now required for all transfers. See Exhibit 20. The new form explicitly requires explanations of the reason for the transfer as well as how the error occurred.

- g. Providing employees' training on the specific types of travel expenses that the College considers non-reimbursable, such as alcohol and airline seat selection fees and training on the documentation needed to support travel costs.*

The College agrees with this recommendation. Senior Finance department staff have met with the individuals responsible for the review of the travel expense reimbursements including staff in the Restricted Funds department, Accounts Payable department, and the Purchasing Department and reinforced the importance of a detailed and thorough review of each travel expense item to ensure

compliance with College policy. Additionally, the Controller's Office will hold a formal training on the Travel Expense Policy with the entire College community in early 2024.

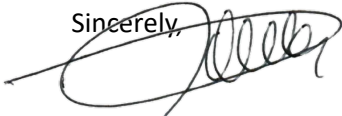
- h. Monitoring key individuals' completion of annual FCOI disclosure forms and completion of required FCOI training.*

The College agrees with this recommendation and, as explained in detail above, has implemented a new integrated FCOI software tracking and record retention platform to ensure full compliance with NIH financial conflict of interest expectations.

* * *

New York Medical College takes its compliance obligations seriously. As indicated above, even when we do not fully agree with the OIG's findings or recommendations, we have made or initiated changes to the College's systems, processes, personnel, and policies to address the findings and recommendations from the audit and to continually improve the College's documentation of compliance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Salomon Amar', written over the word 'Sincerely,'.

Salomon Amar DDS, PhD
Vice President for Research