

# Report on Research Compliance Volume 21, Number 6. May 23, 2024 NY Medical College Clashes With OIG After Audit Questions \$7.5M, PI Salaries, 'Illegible Signatures'

#### By Theresa Defino

New York Medical College (NYMC) officials thought the HHS Office of Inspector General's (OIG) audit was wrapping up in December 2021, based on what "the original senior auditor" told them. But the auditor retired and work continued under a scope that was "significantly expanded, without clear explanation," in the words of Salomon Amar, NYMC vice dean of research and senior vice president for research affairs for its affiliate, Touro University. [1]

It would be another three years before OIG issued the audit, which it posted online May 14. Included is Amar's somewhat blistering 11-page response to a draft of the report, which uses versions of the word "disagrees" five times.

Although the audit "covered 24 NIH awards totaling \$17,172,846," findings stem from an analysis of 92 transactions totaling \$143,508, expended from 2017 to 2019. Auditors also reviewed NYMC's financial conflict of interest (FCOI) disclosures and training to assess compliance with NIH policies.

NYMC's biggest beef with the auditors: a finding questioning "\$7,469,306 in salaries, fringe benefits, and related indirect costs that were unsupported," which they said NYMC should hash out with NIH. But the audit also shows NYMC defending nearly every dollar questioned. For example, NYMC "provided additional documentation supporting \$113 in previously disallowed direct travel costs (\$69) and related indirect costs (\$44)." In terms of repayment recommendations, auditors said they reduced the amount of questioned costs from \$73,628 to \$73,515. NYMC agreed to pay back approximately half this amount.

NYMC also accused OIG of "stubbornly" sticking to a finding it disputed that it violated salary requirements by exceeding NIH's cap and conditioning a principal investigator's (PI) increase on maintaining external funding. Neither Amar nor NYMC's vice president of communications responded to RRC's request for comment on the audit.

For their part, auditors stuck by their conclusions, sometimes using strong (for an audit report) language. For example, "we refute the assertion that we expanded the original scope of the audit," they wrote.

## No Foreign-Related Findings Made

In providing background for the audit, the report noted that "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 [HHS] in terms of meeting program goals and the appropriate use of Federal funds."

As OIG explained, NYMC's report is part of a "series of audits of institutions of higher education, and based on our risk assessment" of NYMC. What the risk assessment revealed is not mentioned. Moreover, auditors did not use the word "foreign" beyond the generic mention in the introduction of the report; NYMC's audit contains no

findings linked to foreign-related issues.

Auditors also called attention to a 2019 report that found more than half of surveyed institutions with NIH awards had not posted FCOI policies online, as required.

According to Amar, the audit "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." After a new primary auditor took over, "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," Amar wrote in NYMC's response.

#### OIG "Systemic Issues" Create "Risk"

OIG auditors contended that NYMC's "procedures for accounting for personal services costs did not produce records that reasonably reflected the actual activity for which employees were compensated." Auditors said their "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."

Given "systemic issues" with NYMC's effort reporting system prior to July 2019, auditors said \$7,469,306 "in salary and wages, fringe benefits, and related indirect costs...were at risk of not being expended for the purposes described" in the awards.

Auditors also concluded that NYMC "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."

In its response, NYMC said this was untrue and that its officials never made such admissions to the auditors. Auditors said NYMC should "work with NIH to determine the allowability" of the \$7,469,306 and "refund any identified overpayments." NYMC committed to working with NIH "to confirm the allowability of the salary, wages, fringe benefits and related indirect costs charged to our NIH awards and take correction (sic) action as appropriate," Amar wrote.

Additionally, auditors said NYMC "incorrectly charged \$73,515 to its NIH awards," which they said should be repaid. Of the total, \$44,763 was attributed to "salary, fringe benefits, and related indirect costs that exceeded the NIH salary cap for calendar years 2017, 2018, and 2019." Auditors also questioned \$3,060 "transferred to an NIH award [for] supplies and related indirect costs" and \$874 "in travel and related indirect costs that were unallowable or were not documented."

NYMC agreed to repay "\$32,871 of over-the-cap expenses (\$20,044 direct and \$12,827 indirect costs) [that] were improperly charged...due to internal errors." However, of another \$11,892 in salaries and related costs that OIG said were unallowable, NYMC agreed to pay only \$849. It also took issue with auditors' characterization that it had conditioned a salary increase on a PI maintaining external funding, which was in violation of NIH requirements. "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," NYMC's response states. In total, NYMC disputed repayment of \$36,095 in costs auditors questioned.

## 'Illegible' Signatures Occurred Amid Shutdown

Auditors reviewed NYMC's "policies and procedures to determine whether [it] had controls in place during our audit period to ensure the allowability of costs in accordance with Federal and award requirements." They looked at NYMC's systems in place before July 2019 and after, following NYMC's implementation of new effort reporting procedures.

"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," auditors wrote. "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."

Auditors "did not identify any errors" among "17 salary transactions totaling \$23,606 that occurred between July 1, 2019, and September 30, 2019." But they found "issues that would not allow us or management to readily determine who signed some effort reports and when the effort reports were signed."

Auditors reviewed 15 time and effort certification reports, finding that five were signed and dated properly, but that for five, "the signature was illegible," and another five were signed but not dated.

NYMC disputed that there were problems with the 10 reports. "There is no federal requirement that time and effort certification reports be signed with a legible signature or that signatures be dated," it said.

Moreover, the five reports deemed illegible "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," according to NYMC's response. NYMC's "Restricted Funds department was scrambling to pick up records before the entire College went remote. The same day as the reports were signed," NYMC officials "exchanged an email with the PI's administrative assistant to arrange for a physical collection of the signed certification reports." NYMC "had full knowledge of the identify (sic) of the report signer, and a sloppy signature by a PI did not negatively impact the accuracy of the report."

Since receiving the draft audit, NYMC "added a typed name line on certification reports," Amar wrote.

#### Not All FCOI Requirements Were Met

To assess NYMC's compliance with FCOI training and disclosure requirements, auditors reviewed the activities of 30 employees—27 assigned to the five awards that were the focus of the audit and three individuals assigned to another award. They also "judgmentally selected an additional 5 personnel assigned to 2 NIH subawards."

NYMC "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," auditors said. They found that NYMC "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."

During the audit period, NYMC "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," according to the report.

In his response, Amar disputed some of these assertions but agreed with auditors' recommendation that NYMC should better monitor FCOI compliance, explaining it instituted a new "integrated FCOI software tracking and record retention platform to ensure full compliance with NIH financial conflict of interest expectations."

Amar concluded NYMC's response with the following: "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."

#### **Similar Reports Had Fewer Findings**

This is OIG's third such audit, but the findings have little in common with the other two, which were both issued last year. OIG found that Illinois State University's costs complied with federal and award requirements and that it "properly maintained training records and monitored disclosures of significant outside activity to meet FCOI requirements associated with the seven employees in our sample who had received NIH awards as Principal Investigator or Co-Principal Investigator." [2]

OIG's audit of Saint Louis University reviewed 31 costs totaling \$426,443. Auditors found that six transactions totaling \$42,578 "did not comply with Federal and award requirements for allowability of costs. These errors occurred because the controls that the University had in place, to include policies and procedures, were inadequate to ensure that the University always managed its NIH awards in accordance with Federal and award requirements." [3] However, auditors recommended that the university repay just \$263 for unallowable travel costs and implement stronger internal controls.

Related to FCOIs, auditors found no issues with Saint Louis's oversight and determined it "had policies and procedures in place that were designed to meet FCOI requirements for training and monitoring of outside interest disclosures."

- <u>1</u> U.S. Department of Health and Human Service, Office of Inspector General, *New York Medical College Claimed Unallowable Grant Costs and Did Not Meet Certain Financial Conflict of Interest Requirements*, A-04-20-03583, May 2024, <a href="https://bit.ly/4blNYJZ">https://bit.ly/4blNYJZ</a>.
- <u>2</u> Theresa Defino, "HHS OIG: Illinois State Complied With Spending, FCOI Requirements," *RRC* E-Alerts, October 12, 2023, <a href="https://bit.lv/3QQPlrQ">https://bit.lv/3QQPlrQ</a>.
- **3** U.S. Department of Health and Human Service, Office of Inspector General, Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements But Complied With Financial Conflict of Interest Requirements, A-07-20-05127, June 2023, <a href="https://bit.ly/4asiz7j">https://bit.ly/4asiz7j</a>.

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