

## Report on Research Compliance Volume 20, Number 6. May 25, 2023 In This Month's E-News: June 2023

By Theresa Defino

♦ After reviewing recommendations from its Office of Inspector General (OIG), the National Science Foundation (NSF) required Yale University to repay \$172,213 of the \$251,973 auditors flagged in a 2020 report. According to a May 11 audit resolution, NSF permitted \$79,760 of expenditures auditors said were unallowable. The audit encompassed \$96 million in costs claimed among 465 NSF awards expended from Feb. 1, 2016, to Jan. 31, 2019. Auditors tested 250 transactions representing \$3.9 million in expenditures. The largest portion of costs NSF allowed was \$58,577, which auditors said were for lasers used only in the final months of two awards. However, NSF agreed with Yale and "determined that the lasers were calibrated specifically for the NSF research and that no other research performed at the time of purchase could have benefited from the lasers without re-calibration; therefore, 100% of the cost of the lasers is allocable to the respective NSF awards." The agency also said it approved of Yale's implementation of OIG's recommendations to "enhance internal controls over approval of equipment and material purchases near award expiration; strengthen allocation method to charge equipment, materials/supplies, travel, and other direct costs; approval of publication costs; and, approval of travel expense reports."

Additionally, without stating a reason, NSF allowed \$16,404 of \$39,850 auditors questioned that Yale incurred for professional services under an agreement OIG said was "not appropriately executed." NSF agreed with OIG that Yale "did not follow its procurement policy. Rather than: (1) rejecting the invoice when it was presented for payment; (2) requiring that the value for services received go through a ratification process, and (3) properly procuring the remaining services, Yale approved and paid a three-year prepayment invoice." (5/18/23)

♦ Administrative burdens and costs required to comply with NIH's newly expanded data management and sharing (DMS) policy, which went into effect in January, are "significant," totaling more than \$1 million per year, according to a survey of research institutions conducted by the Council on Governmental Relations (COGR). As COGR explained, "large NIH sponsored research projects (above \$500,000 in direct costs) already were subject to these DMS requirements [but] the new policy is now applicable to all NIH projects that result in the generation of scientific data."

The survey reflects responses from 16 public and 13 private institutions that had \$100 million in federal research and development funds per year and four public and one private with less than this amount. To calculate compliance costs, institutions tallied expenditures in 11 units or areas, such as pre-award, post-award and institutional review boards, and five activities, including data planning, integrity and storage. "While NIH has created some mechanisms to share in the cost of compliance, implementation of these mechanisms is uncertain," COGR noted. "It is clear current cost reimbursement mechanisms available to research institutions ensure that the federal government will not bear its fair share of costs. Consequently, every new federal regulation issued is effectively an unfunded federal mandate," and, if not addressed, will whittle away at "participation in the federal research ecosystem" and impose burdens that force researchers into other fields. (5/18/23)

♦ Facing a dwindling number of nonhuman primates (NHPs), NIH-funded investigators are experiencing "skyrocketing" increases in cost of up to 200% per animal and are being forced to scale back significant studies,

"undermining the U.S. biomedical research enterprise and national health emergency readiness," according to a new report by the National Academies of Sciences, Engineering, and Medicine. The authors fault NIH for "inadequate coordination of research programs at the national level" and for not fully implementing recommendations in a 2018 NIH report, but also blame a Chinese export ban enacted in 2020 as contributing to the shortage. "The development and implementation of a national plan for nonhuman primate research resources would help ensure the availability of these important research models to meet the nation's public health needs," they suggested. Other recommendations include importing nonhuman primates and breeding them in the United States.

NHPs include rhesus macaques, baboons, marmosets and African green monkeys. In 2015, NIH started phasing out research involving chimpanzees and other great apes in most biomedical research but continues to support research with other types, albeit at declining funding levels. Based on investigators' survey responses, the report found overall NHPs used in federally supported research had declined over the past decade. "A more than 20 percent reduction in cynomolgus macaque imports was reported in 2020 following China's export ban, highlighting the vulnerability of NHP research caused by undue reliance on imported NHPs subject to geopolitical pressures and logistical constraints that jeopardize reliable access," the report adds. "Approximately 64 percent of respondents to the [study] committee's survey reported challenges with obtaining NHPs for their currently funded NIH awards. For greater than half of all active NIH awards reported by survey respondents, fewer NHPs were enrolled than originally planned. ... Impacts of NHP shortages have included increased wait times for NHP enrollment in studies," according to the report. "It is now time for the nation's leaders to take the action necessary to ensure that the United States maintains its scientific leadership and that biomedical investigators nationwide have the tools necessary to advance vital NIH-supported biomedical research," said study committee chair Kenneth Ramos in the preface to the report. "Indeed, patients are waiting." Ramos is also the associate vice president for research at Texas A&M University Health Science Center. NIH funded the study, which does not include agency responses to the recommendations. (5/11/23)

♦ In the first audit resolution report posted so far this year, NSF required the West Virginia University Research Corporation to repay \$43,156, the full amount OIG auditors flagged during a review of award expenditures from Sept. 1, 2017, to Aug. 31, 2020. According to the April 20 report posted online, auditors questioned \$17,335 in purchases near or after award expiration, \$23,018 in unallowable and unreasonable costs and \$2,803 in unallowable indirect costs. "NSF conducted detailed reviews of applicable Federal and NSF requirements, proposal and award information maintained by NSF, and documentation provided by" the university, the agency said. Unlike most other resolution reports, NSF did not say the university agreed with its decision, but indicated the total sum had already been repaid. However, the audit itself, issued July 5, 2022, said the university agreed with the findings.

The audit covered \$25.9 million of costs claimed to NSF; auditors tested \$1.5 million in transactions. According to the audit, the \$17,335 included two computers, an iPad, supplies, stock room charges and conference registration; the iPad was purchased seven days after expiration and one computer was acquired with 32 days left on the award, while conference registration was expended 103 days after award expiration. Among the \$23,018 in unallocable and unreasonable expenses were five transactions charged to four awards, consisting of a \$10,650 liquid helium recovery system, \$7,800 in publication fees, \$4,256 in travel (the destination is redacted) and \$235 for AirPods. Auditors said the helium charges should have been made across several awards. The university said publication fees were errors. Auditors said the AirPods "were useful for listening to webinars" but "were not used exclusively on the NSF award." (5/11/23)

♦ On April 26, U.S. Senior District Court Judge Rya W. Zobel sentenced Charles Lieber, former Harvard University chair of the Chemistry and Chemical Biology Department, to two days in jail, time he already served, and six months of home confinement as part of two years of supervised release. The sentence, which also included a

payment of \$83,600, ends one of the most high-profile cases in the government's "China Initiative" that sought to protect research from untoward foreign influences but was criticized for unfairly targeting scientists of Asian descent. Cases against other investigators have been dismissed or resulted in convictions on far fewer charges with no jail time. Unlike Lieber, most of those investigators were not paid by a foreign university or talent program.

Lieber was convicted in December 2021 on six charges related to lying to FBI investigators and hiding payments from Wuhan University of Technology (WUT) and his affiliation with a Chinese talents program. Lieber signed a three-year contract with a talents program in 2012 and, according to the government, "performed many of the duties and responsibilities required of him under that contract, and been paid a substantial salary by WUT in exchange for his work. Specifically, the terms of Lieber's three-year Thousand Talents contract with WUT entitled Lieber to a salary of up to \$50,000 per month, living expenses of up to \$150,000 and approximately \$1.5 million to conduct joint research at WUT." His sentence includes a fine of \$50,000 and \$33,600 in restitution to the IRS for failing to file reports of foreign bank and financial accounts, according to the U.S. Attorney's Office for the District of Massachusetts. "The government recommended a sentence of 90 days in prison and a \$150,000 fine," the office said. (5/4/23)

♦ The former director of a cancer center at Rosalind Franklin University of Medicine and Science has retained his professorship there despite agreeing to a three-year period of supervision for committing research misconduct that the HHS Office for Research (ORI) announced on April 17. Johnny J. He joined the university in 2020 as director of the Center for Cancer Cell Biology, Immunology and Infection, according to the university's website. A year later, He "engaged in research misconduct by intentionally, knowingly, or recklessly falsifying, fabricating, and plagiarizing experimental data and text" and representing the "data and/or ideas as his own under different experimental conditions" in four grant applications and a "research record" used to "prepare figures" for an application.

In an unusual move, ORI also listed the sources of the faked data—five papers published from 2017 to 2021. Beginning April 17, He agreed that, prior to submitting an application for Public Health Service (PHS) support, he will submit to ORI a plan for his supervision "designed to ensure the integrity of [He's] research. A committee of senior faculty members familiar with He's research will "provide oversight and guidance," review primary data from his lab and submit reports to ORI at six—month intervals assuring He is complying with "appropriate research standards." During the reporting period, He also agreed he will not serve as a peer reviewer or an advisor in any capacity to PHS. (5/4/23)

This publication is only available to subscribers. To view all documents, please log in or purchase access.

Purchase Login