

Report on Research Compliance Volume 18, Number 9. August 26, 2021 In This Month's E-News: September 2021

By Theresa Defino

◆ **A former Harvard Medical School and Massachusetts General Hospital (MGH) researcher who was the principal investigator on a 2014 NIH award of \$939,495.27 and allegedly fabricated data in the award application has agreed to pay the government \$215,000.** The payment resolves potential violations of the False Claims Act that resulted from Sam W. Lee's alleged research misconduct, the Department of Justice announced Aug. 6. MGH conducted an "internal review," according to the settlement, and then "stopped drawing federal funds for [Lee's award] and voluntarily disclosed to the United States that Dr. Lee allegedly submitted grant applications to NIH containing inauthentic data. MGH repaid NIH the full amount of funds it received, \$939,495.27." It is not clear when MGH's repayment and the disclosure were made. (8/19/21)

◆ **A former associate professor at Mount Desert Island Biological Laboratory agreed to a two-year supervisory plan and to request that three papers be retracted because they contain fabrications or falsifications, according to a notice by HHS Office of Research Integrity (ORI).** In only its second finding of the year, ORI said Viravuth Yin "neither admits nor denies ORI's findings of research misconduct." According to the Aug. 16 post on the agency's website, Yin "engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying and/or fabricating data" in three published and two submitted papers. One of the publications was itself a correction. The papers were published in 2015 and 2019; the unpublished manuscripts were submitted in 2018. Yin, ORI said, had reused and relabeled phosphate buffered solution controls as locked nucleic acids in 21 experiments and then created false images and data. ORI also cited five instances where Yin did not perform experiments but nonetheless reported "research methods and statistics." (8/19/21)

◆ **With the completion of its 10 reviews of universities' implementation of COVID-19 administrative flexibilities granted by the Office of Management and Budget (OMB) last year, the National Science Foundation (NSF) Office of Inspector General (OIG) has issued a "capstone" report on its findings.** The picture it paints is of the flexibilities providing some level of assistance but also of award recipients not making full opportunity of them, sometimes out of fear born of less-than-ideal implementation across the federal government. "Because OMB required federal agencies to issue their own guidance regarding whether and how recipients should implement the COVID-19 flexibilities, recipients did not believe they had access to sufficient, timely guidance that would allow them to ensure they were able to appropriately implement the flexibilities granted by each agency," the Aug. 3 report said. "Further, because federal agencies were not always timely in publishing comprehensive agency-specific guidance, many recipients were unable to implement the flexibilities and/or relied on guidance published by non-regulatory bodies." (8/12/21)

◆ **Investigators whose awards require training in the responsible conduct of research will be able to take such courses online through the end of this year, rather than in-person, NIH officials announced Aug. 2.** NIH, along with the Agency for Healthcare Research and Quality and Health Resources and Services Administration, said it was extending this option, or flexibility, that had initially been granted last year as a result of the COVID-19 public health emergency. The flexibility will exist "even if the declared public health emergency is rescinded before then," and is being extended to help "universities in their planning for the 2021-2022 academic year," the notice said. (8/12/21)

◆ **HHS OIG plans to undertake something of an unusual kind of study, according to an update of its work plan** Recognizing that “underrepresentation of racial and ethnic minorities, women, and individuals of all ages in clinical trials has been a longstanding concern,” exacerbated by the “COVID-19 pandemic’s disproportionate impact on minority populations,” HHS OIG plans to review “how NIH monitors and ensures enrollment” of these groups as well as NIH’s actions “in response to clinical trials that are not meeting approved enrollment plans.” (8/5/21)

◆ **NSF OIG has completed its 10th audit of a university’s use of administrative flexibilities in spending NSF awards as offered by OMB and again found no problems or “exceptions.”** However, like some of the others, auditors questioned costs unrelated to flexibilities granted during the pandemic. In conducting an audit of the University of Michigan (UM), dated Aug. 2, OIG tested 39 transactions totaling \$1,006,989, “and identified four examples in which UM used the COVID-19 flexibilities,” which affected just \$36,896.

Of this amount, \$30,053 was for “equipment, materials, and supplies that UM has not yet used to benefit the award, as the Principal Investigator’s (PI’s) laboratory remained closed as of the completion of our audit fieldwork”; \$2,686 was for “airfare expenses purchased to enable student researchers to return home earlier than anticipated due to COVID-19”; there was “2,830 in airfare expenses associated with a cancelled flight”; and \$1,327 in hotel expenses associated with a cancelled trip. As OIG explained, “these expenses are not typically allowable on NSF awards” but were okayed “because these costs relate to the cancellation of events and other activities necessary and reasonable for the performance of these awards.” OIG recommended that UM improve its oversight of travel credits. It also questioned a total of \$11,499 for “unallowable rebudgeted participant support cost funding.” OIG did not find misspending but said UM did not seek NSF approval for the rebudgeting. UM agreed to make repayment of this amount. (8/5/21)

◆ **NSF OIG auditors questioned approximately half of the costs of sampled expenditures claimed by Tennessee State University on NSF awards, but TSU believes most are appropriate.** According to the July 20 report, OIG tested 80 transactions totaling \$305,526 among approximately \$5.9 million in costs TSU claimed on 11 awards from June 1, 2014, to July 25, 2019. Overall, OIG questioned \$155,432 of the tested expenditures; TSU agreed to make repayment of only \$28,859. OIG also found issues with TSU’s effort certification process. The largest portion of the questioned costs, \$121,797, was related to four grants, and consisted of \$66,169 of stipend charges and \$55,628 of payroll charges OIG said were unallowable because “TSU did not provide documentation to establish the appropriate amount or nature of these stipends as participant support costs, employment payments, or scholarships.” TSU “agreed that \$19,571 of indirect costs should not have been charged,” but stated that “10 of the 11 payroll transactions are allowable, allocable, and reasonable. TSU believes that the time and effort reports were completed as required but due to staffing and personnel changes, the original reports could not be located. For the one remaining unsupported salary cost, TSU agreed to return the \$2,415 to NSF,” OIG said.

Another \$16,885 was inappropriately allocated expenses for four awards, consisting of “\$11,371 related to charges for equipment and supply costs, \$2,797 related to payroll costs, and \$2,717 related to unallowable general ledger costs.” OIG determined that some of the costs were incurred within days of the end of the award period of performance. “TSU agreed to return \$5,514 but disagreed with the remaining \$11,371 in questioned costs,” according to the audit. Auditors also made 13 recommendations. NSF will make a final determination on what amounts, if any, TSU will need to repay and any changes it should make to its policies and procedures. (7/29/21)

◆ **A indictment unveiled this month charges four Chinese residents with undertaking a seven-year “campaign to hack into the computer systems of dozens of victim companies, universities and government entities in the United States and abroad.”** A federal grand jury in San Diego found that the four targeted “information that was of significant economic benefit to China’s companies and commercial sectors, including information that would allow the circumvention of lengthy and resource-intensive research and development processes.” As the DOJ

announced July 19, “to gain initial access to victim networks, the conspiracy sent fraudulent spearphishing emails, that were buttressed by fictitious online profiles and contained links to doppelgänger domain names, which were created to mimic or resemble the domains of legitimate companies. In some instances, the conspiracy used hijacked credentials, and the access they provided, to launch spearphishing campaigns against other users within the same victim entity or at other targeted entities.” Additionally, the individuals “used multiple and evolving sets of sophisticated malware, including both publicly available and customized malware, to obtain, expand and maintain unauthorized access to victim computers and networks.” (7/29/21)

The NIH Office of Laboratory Animal Welfare (OLAW) is seeking comments on new draft “clarifying guidance” regarding the type of deviations from the *Guide for the Care and Use of Laboratory Animals* that should be reported by institutional animal care and use committees (IACUC) to institutional officials. As OLAW explained in a request for information (RFI) posted on July 20, “the purpose of the *Guide* is to assist institutions in caring for and using animals in a scientifically, technically, and humanely appropriate manner. It also assists investigators in fulfilling their obligation to plan and conduct animal experiments according to the highest scientific and ethical principles.” (7/29/21)

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