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By Theresa Defino

◆ In a review of more than 500 NIH awards, the HHS Office of Inspector General (OIG) found that about one-fifth were funded “out of rank order,” and for more than a third of those, “no reasoning was documented”—a violation of HHS policy. “That means that NIH lacks insight into whether the ICs [institutes and centers] are funding out of rank order to further NIH’s mission or because of problems that warrant NIH’s attention,” OIG said in the report released June 15. The agency explained that “NIH’s grantmaking process provides ICs with discretion to fund a grant application that was ranked less favorably by the first level of peer review over an application that was ranked more favorably. Funding out of rank order allows the ICs to fund grants that align with their research priorities or that address emerging threats to public health, for example.” OIG reviewed fiscal 2018 data for awards made by the National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Drug Abuse and several others.

All told, “ICs funded 109 of the 540 grants in our sample out of rank order,” but this was highly variable. For example, NIDDK “funded 67 of its 130 sampled grants out of rank order,” while NINDS “funded 8 of its 184 sampled grants out of rank order.” NIH was amenable to OIG’s recommendations for changes to increase transparency. “NIH stated that it will develop structured data for identifying, tracking, and providing compliance oversight on grants awarded out of rank order, with implementation planned for fiscal year 2021,” OIG said. “NIH also stated it will conduct a comprehensive review in the same year, and implement further internal controls, guidance, and compliance testing as needed based on the results of the review.” Further, NIH will revise “its internal policy and staff guidance to reflect the requirement of the HHS Grants Policy Administration Manual to tie funding justifications to factors documented in the Funding Opportunity Announcement.” (6/17/21)

◆ “A friendly word of caution to the research community—with the rise of biobanks/large datasets in the 21st century, researchers should pay particular attention to data rights restrictions and carefully vet the use of any data source before using it for scientific purposes.” Those words of advice came from a research team at the University of West Virginia to *Retraction Watch* after they were forced to request that a journal remove a paper they published just three months ago about alopecia. According to comments first author Ahmed Yousaf made to *Retraction Watch*, the research team requested, and thought it had obtained, permission to use the data from UK Biobank that was the basis for the paper that appeared in *JAMA Dermatology*.

The biobank outpatient dataset was restricted to studies involving COVID-19 research, and the group published one such paper. The team had “requested the primary care data without COVID restrictions,” he said, and was “shocked” by the biobank’s notification that use for the alopecia study had not been granted. Yousaf told *Retraction Watch* he wasn’t sure if the team would submit a new request for permission following the retraction. “It was unfortunate to pull an otherwise ethically sound paper with a strong premise, we agree with the UK Biobank that appropriate data use and participant protection trumps the value of any publication,” Yousaf said. (6/17/21)

◆ Although randomized clinical trials are considered the gold standard, “their analytic plans may be

inappropriate and have inadequate power due to small sample sizes,” according to David M. Murray, NIH associate director for prevention and director of its Office of Disease Prevention. “To have a strong and rigorous study, researchers should provide sufficient information on the selected methodology, statistical analysis, and sample size when proposing a trial,” he continued in a June 9 guest post on the *Open Mike* blog. (6/17/21)

◆ **Watchdog organization Public Citizen is urging the Office for Human Research Protections, the Food and Drug Administration and NIH Director Francis Collins to investigate an NIH-funded trial of epilepsy treatments that enrolled more than 400 subjects at 58 U.S. hospitals.** In June 8 letters to the agencies, Michael Carome, M.D., director of Public Citizen’s Health Research Group, said the goal of the Established Status Epilepticus Treatment Trial was to assess whether one of three anticonvulsant drugs would “result in better seizure resolution and responsiveness within 60 minutes after initiation of the assigned drug, without additional anticonvulsant medications,” in patients who had already been treated with benzodiazepines following a seizure. (6/10/21)

◆ **Two employees of Tellus Clinical Research in Miami pleaded guilty to falsifying data in two clinical trials for irritable bowel syndrome, the Department of Justice (DOJ) announced June 8.** Eduardo Navarro was a sub-investigator and Nayade Varona was an assistant study coordinator. “As part of their plea agreements, Navarro and Varona admitted that they agreed with one another and others to falsify data in medical records in connection with two clinical trials intended to evaluate a treatment for irritable bowel syndrome. Among other things, Navarro and Varona falsified data to make it appear as though subjects were participating in the trials when, in truth, they were not,” according to DOJ. “Both face a maximum penalty of five years in prison and are scheduled to be sentenced on Aug. 11,” the government said. (6/10/21)

◆ **Auditors for the National Science Foundation (NSF) OIG reviewing California Institute of Technology’s (Caltech) implementation of COVID-19-related administrative flexibilities granted by the Office of Management and Budget (OMB) found a single exception or irregularity, apparently the first problem among nine such reports OIG has issued.** Caltech’s audit was one of seven such audits issued last month. According to the May 26 report, auditors “questioned \$16,769 of unallowable salary charged” on several awards after OMB’s memorandum on flexibilities “expired.” However, Caltech officials disagreed with the auditors regarding this finding. The funds were for “employees who could not perform their jobs through” July 19, 2020, and OMB’s flexibility period ended June 16, 2020, Caltech acknowledged. But officials argued that “it was unreasonable for OMB to have discontinued the flexibilities...without a retirement period” and that OMB should have defined “exhaust other available funding sources.” (6/10/21)

◆ **Following a guilty plea in November on one count of making false statements on NIH applications, a former Ohio State University rheumatology professor will serve a prison term of 37 months and repay OSU \$413,000 and NIH “more than” \$3.4 million, DOJ recently announced.** Song Guo Zheng was arrested a year ago in Alaska “as he prepared to board another charter flight in order to flee to China. He was carrying three large bags, one small suitcase and a briefcase containing two laptops, three cell phones, several USB drives, several silver bars, expired Chinese passports for his family, deeds for property in China and other items,” according to DOJ.

Zheng did not disclose to OSU nor NIH that he had been participating since 2013 in China’s Thousand Talents program, used “to recruit individuals with knowledge or access to foreign technology intellectual property.” He received \$4.1 million from NIH “to develop China’s expertise in the areas of rheumatology and immunology,” the government said. Zheng worked at the University of Southern California and Pennsylvania State University before joining OSU in 2019. “Zheng’s failure to disclose his foreign funding and support damages the trust and undermines the credibility the American people place in U.S. research, while abusing the openness and transparency that is a core value of U.S. academia,” said Special Agent in Charge Chris Hoffman for the FBI’s Cincinnati Field Office. “This sentence should serve as a deterrent and underscores the FBI’s commitment to work with our partners to investigate individual’s whose actions throw a cloud over the cutting-edge work being

done at U.S. universities.” (5/27/21)

◆ In the third such audit of how universities handled COVID-19-related award flexibilities granted by OMB, auditors for the NSF OIG said Florida International University (FIU) complied with OMB guidance, but found several unrelated issues that OIG said require attention. According to the May 19 report, auditors “tailored our data analytics sampling approach to enable us to select 31 transactions that FIU incurred in accordance with the COVID-19 flexibilities, or that we identified as high risk for other related reasons” that were handled from March 1 to Sept. 30. “The audit encompassed approximately \$208,000 of the more than \$12.4 million claimed to NSF during the period,” they noted.

While finding no “exceptions” or misuse of the flexibilities, auditors said FIU could “improve its administration of flexibility-related expenses charged to NSF awards related to monitoring of travel credits. The auditors also identified concerns about FIU’s compliance with certain Federal and NSF regulations, NSF award terms and conditions, and organizational policies not related to the COVID-19 flexibilities,” according to the report. “Specifically, the auditors identified \$15,419 in inappropriate Award Cash Management Service drawdowns and \$6,725 in unallowable expenses.” They also found there was an “incorrect application of unapproved fringe benefit rates.” FIU “agreed to correct the clerical error that caused it to inappropriately draw down \$14,167 on one NSF award but disagreed with the \$1,252 in questioned costs related to expiring appropriations,” OIG said. (5/27/21)

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