

## Report on Research Compliance Volume 17, Number 4. March 26, 2020

### In This Month's E-News: April 2020

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By Theresa Defino

◆ **The Food and Drug Administration has accused a University of Michigan physician and professor of conducting research for more than three years after his approval from the agency expired, according to one of the first investigator warning letters FDA has published in many months.** FDA's Feb. 27 letter to James Corbett, MD, follows a July 2019 inspection and seeks more information than it received from him at that time. According to his bio on the University of Michigan website, Corbett is a professor of medicine and specialist in myocardial perfusion imaging. The FDA letter does not specify what drug he was studying or the type of research. FDA said it terminated Corbett's investigational new drug (IND) application in June 2014 because he had failed to file a required annual report for at least two years. According to FDA, Corbett never obtained a new IND but continued enrolling 18 subjects and gave them a study drug up until January 2018. "Thus, subject safety and rights were compromised for a period of more than 3 years," the agency said based on its 2019 inspection. The agency also said Corbett had failed to notify the institutional review board that the IND was terminated and had enrolled a subject who should have been excluded based on a health condition. (3/19/20)

◆ **NASA awardees will have to report findings of sexual and other forms of harassment to the agency within the same parameters as the institutions with National Science Foundation (NSF) funding,** NASA announced in a final rule published in the March 10 *Federal Register*. The new term and condition applies to actions taken against principal investigators and co-PIs.

Institutions are required to notify NASA within 10 business days of any "finding/determination regarding the PI or any [co-PI] that demonstrates a violation of the [award] recipient's policies or codes of conduct, relating to sexual harassment, other forms of harassment, or sexual assault; and/or if the PI or any [co-PI] is placed on administrative leave or if any administrative action has been imposed on the PI or any Co-PI by the recipient relating to any finding/determination or an investigation of an alleged violation of the recipient's policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault." NASA noted that it has "fully aligned its reporting requirements" with NSF's. The effective date is 30 days from publication. "The new term and condition will be applied to all new NASA awards and funding amendments to existing awards made on or after the effective date. This new reporting requirement will apply to all findings/determinations that occur on or after the effective date of the terms and conditions," NASA said. (3/19/20)

◆ **An audit by the HHS Office of Inspector General (OIG) of 116 NIH awards active from October 2017 through September 2018 found that "grantees did not receive duplicate NIH grant funding," because the agency has effective internal controls.** Congress's 2019 appropriations legislation required the audit as part of the "larger body of HHS-OIG oversight work related to NIH grant programs and operations," OIG explained in the March audit. NIH's process is to check for duplication during the just-in-time process.

To conduct the audit, auditors "held discussions with NIH officials and reviewed NIH's policies and procedures for identifying duplicate grant funding." For the selected grants, which totaled \$33.1 million, OIG "identified similar grants...using NIH's Matchmaker data mining tool" to look for duplication. After using "text recognition

software,” auditors “reviewed the grant documentation of each similar grant to determine if grantees received duplicate NIH grant funding,” OIG said. Given that no duplication was found, OIG did not make any recommendations and NIH did not comment on the audit. (3/19/20)

◆ **The HHS Office for Human Research Protections (OHRP) recently posted two determination letters reflecting unrelated investigations into possible noncompliance by the University of Alabama at Birmingham (UAB) and Tulane University, stemming from complaints received in 2016 or earlier.** The letters are the first OHRP has issued since March 2019; in all of last year, the agency only posted two. In its Jan. 28 determination letter to Tulane, OHRP said it concluded that allegations of improprieties among its institutional review board (IRB) were unfounded. OHRP did not post anything but this letter to Tulane, but apparently there was a series of four additional queries back and forth between the agency and Tulane, beginning in July 2016. A complainant alleged that the chair of Tulane’s biomedical IRB was violating conflict of interest regulations by also serving as the director of its Clinical Trial Unit and that other IRB members also were employees of the CTU. OHRP said it “does not consider an IRB member’s affiliation with a CTU as an automatic conflict of interest” and that Tulane had “provided evidence demonstrating that the IRB Chair/CTU Director and staff regularly recused themselves from votes to avoid potential conflicts of interest” as required. A related complaint was that two members were improperly designated as “non-scientific”; this allegation was also unproven, OHRP said. Nevertheless, Tulane apparently instituted a number of changes as a result of OHRP’s investigation, according to the determination letter, including naming a new chair who is unaffiliated with the CTU and creating a “Compliance Work Group to review and investigate potential instances of serious or continuing non-compliance identified by the IRB.” (3/12/20)

◆ **Elisabeth Handley, who has served as the interim director of the HHS Office of Research Integrity for the past seven months, has been named to the post permanently, according to a March 3 announcement on the ORI website.** ORI is responsible for making findings of research misconduct, defined as fabrication, falsification and plagiarism, in Public Health Service-funded research. ORI has been roiled by a series of leadership departures during the past several years and still remains short one division director. Handley was named interim director in August, replacing Wanda Jones, who had been the interim director since December 2017, following the departure of Kathy Partin from the top post. In the March 3 announcement, HHS also stated that Jones has been named associate director for research and scientific integrity, which appears to be a new title within ORI. She will also continue as the deputy director, a position to which she was appointed in June of last year after serving as the acting deputy. (3/5/20)

◆ **As part of its response to recommendations by the JASON advisory group on combating inappropriate foreign influences in U.S.-funded research, NSF has created a new position of chief of research security strategy and policy.** NSF appointed Rebecca Spyke Keiser, who has led NSF’s Office of International Science and Engineering since 2015, to the post, the agency announced March 2. Keiser will provide NSF’s director “with policy advice on all aspects of research security strategy” and spearhead NSF’s “efforts to develop and implement strategies to improve research security and the agency’s coordination with other federal agencies and the White House,” NSF said.

NSF also described other efforts stemming from the JASON report, although the new post may be the only clear example of a specific, new action. Others, such as a clarification of disclosure requirements, have recently been put in place. NSF representatives are serving on the Office of Science and Technology Policy’s Joint Committee on Research Environments. NSF outlined other possible efforts, such as “reviewing its internal science and security training modules to adapt them for potential external use.” The agency said it and its partners remain “committed to a principle outlined in the JASON report: that these threats stem from the governments of China and other foreign nations, not from foreign-born scientists or those of foreign descent. Foreign-born scientists who train and work in the United States are critical to the health of our innovation economy.” (3/5/20)

◆ NIH’s Clinical Center is host to more than 1,600 labs conducting basic and clinical research, accommodates 1,300 physicians, dentists and PhD researchers, and handles approximately 95,000 outpatient visits and 4,500 inpatient admissions, according to 2018 data. At its heart is the Clinical Research Information System (CRIS), which contains the Clinical Center’s electronic health records (EHR) system. According to the HHS OIG, “data and the IT [information technology] security controls protecting the data are of significant importance” to HHS and the federal government. But a recent OIG audit found that, while NIH “had certain controls in place to secure EHR information and information system,” its “information security policies and practices were not operating effectively to preserve the security, confidentiality, integrity, and availability of NIH's EHR information and information systems, resulting in potential risks of unauthorized access, use, disclosure, disruption, modification, or destruction.” (3/5/20)

◆ An assistant professor with the Institute for Simulation and Training at the University of Central Florida (UCF) successfully appealed his proposed termination and returned to work Feb. 24, but the firing of an IST associate professor is proceeding, RRC has learned. UCF announced Jan. 27 that it was taking steps to terminate Daniel Barber, Lauren Reinerman-Jones and IST Director Randall Shumaker after a “lengthy investigation found they were involved in helping a student obtain a doctoral degree in exchange for grant funding and with inappropriate assistance from faculty advisors and others.” Shumaker retired Feb. 7, but both Barber and Reinerman-Jones appealed their proposed terminations, using the same attorney and making nearly identical arguments, including that the allegations were vague and unproven and that their due process rights were violated. (2/27/20)

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