

## 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)

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