COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 15, Number 4. April 30, 2018
RRC E-Alerts: April 2018

By Theresa Defino

The following are summaries of news transmitted to RRC subscribers this month in email issues, the date of which is indicated in parentheses following each item. Weekly email and monthly print issues of RRC are archived on your subscriber-only website. Please call 888.580.8373 or email service@hcca-info.org if you require a password to access RRC's subscriber-only website or are not receiving weekly email issues of the newsletter.

- HHS has received fewer than three dozen comments on its interim final regulation that would delay both the effective and compliance dates of the revised Common Rule by six months, and a handful of those appear unrelated. The rule sets July 19 as the date by which the revised Common Rule governing federally supported human subjects research must be implemented (RRC 2/18, p. 1). March 19 is the deadline to comment. Published just days before the original compliance date, the interim final rule was another twist in a seven-year saga to update the Common Rule. In contrast to past rules that generated thousands of comments, regulations.gov shows receipt of 32 comments on the interim final rule, of which 28 are posted. One refers to problems with China's "material dumping actions," while another asserts that activists "and bullies are pushing the unrest in our children by increase (sic) use of Online devices." (3/15/18)

- On the heels of its quest to "publish reports about institutional investigations into misconduct," Retraction Watch convened a group of experts in December that led to the development of a checklist published in the March 12 Journal of the American Medical Association. As described in a "viewpoint" published with the checklist, the goal is to help universities "strengthen plans and reports for investigations into research integrity before they are finalized." (3/15/18)

- NIH is asking for stakeholder input on a draft version of its new Strategic Plan for Data Science, the agency announced March 5. "Data science is an integral component of modern biomedical research. It is the interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are developed and used to extract knowledge and insights from increasingly large and/or complex sets of data," the agency said. "Data science has increased in importance for biomedical research over the past decade and NIH expects that trend to continue." (3/8/18)

- Akbar Fard, the former principal investigator for Advanced Materials Technology, Inc., based in Tampa, Florida, faces up to 20 years in prison when he is sentenced in May following a wire fraud conviction. A jury found Fard guilty of defrauding NASA, the Missile Defense Agency and the U.S. Navy of $2.1 million in awards he received through the agencies' Small Business Innovation Research and Small Business Technology Transfer programs going as far back as 2004. His sentencing hearing is scheduled for May 24, according to a Feb. 12 announcement by Maria Chapa Lopez, the U.S. Attorney for the Middle District of Florida. "Fard thwarted the fundamental purpose of these programs by using the funds to support his lifestyle instead of purchasing research materials," the announcement said. Among the purchases cited in court documents are "mulch, goofy string, groceries [and] family vacations." (3/1/18)

- Registration is open for a free, two-and-a-half-day event on plagiarism scheduled for next month that is supported by funding from the HHS Office of Research Integrity. The "Conference on the Identification,

Processing, Prevention & Cultural Context of Plagiarism," cosponsored by Indiana University and Purdue University, is planned for April 3-5 in Indianapolis. A conference goal is to "provide a comprehensive, workshop-style analysis of plagiarism in relation to the definition of research misconduct and our cultural understanding of plagiarism," according to the meeting announcement. The program is geared toward research integrity officers, their support staff, and responsible conduct of research educators. Discussions will offer "resources concerning how to understand plagiarism from a national and international perspective, as well as how the federal government examines plagiarism and trends in their cases. Additional resources concerning how to understand and complete research misconduct case process surrounding plagiarism, approaches to correcting the research record, and institutional guidance on the prevention of plagiarism will be shared." (3/1/18)

- The National Science Foundation is "previewing the new Research.gov proposal preparation functionality to the research community to collect preliminary feedback and to provide the community an opportunity to acclimate to the new technology," NSF announced in an email on Feb. 26. A formal rollout is planned for April 30. "Your feedback on the new Research.gov proposal preparation functionality during the preview period," which ends April 27, "is vital to NSF," the agency said. It is also soliciting comments on the "full Research.gov proposal preparation and submission functionality after the initial release on April 30. Feedback from the community and NSF staff will be used to implement enhancements and expand functionality incrementally, with the goal of eventually transitioning all proposal preparation and submission functionality from FastLane to Research.gov," the agency said. (3/1/18)

- In its first research misconduct finding of 2018, the HHS Office of Research Integrity (ORI) announced that Colleen Skau committed research misconduct when she was a postdoctoral fellow at the National Heart, Lung, and Blood Institute. In a Feb. 19 announcement posted on its website, ORI said Skau falsified, fabricated and otherwise skewed data in dozens of instances and reported them in two published papers. The papers, on mouse cells and cancer metastasis, both purported to reflect certain discoveries, but ORI said Skau had engaged in selectively reporting "inappropriate inclusion/omission or alteration of data points," among other misconduct. Published in the Proceedings of the National Academy of Sciences in 2015 and in Cell in 2016, the papers will be corrected or retracted as part of the settlement. Skau agreed to have her work supervised if she were to receive Public Health Service funding and to refrain from advising the government during a three-year period beginning Jan. 25. (2/22/18)

- On Feb. 20, the Food and Drug Administration (FDA) published a final rule, "Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices." FDA said the rule updates and clarifies "standards to ensure that the data submitted by device companies for FDA premarket review conform with good clinical practice principles for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical investigations." Such principles, FDA said, "include review and approval by an independent ethics committee, as well as obtaining and documenting study participants' informed consent." FDA called the rule reflective of "the increasing globalization of clinical investigations and the evolution of standards for protecting human subjects." FDA simultaneously issued guidance on the topic. The rule, which goes into effect Feb. 21, 2019, finalizes a proposed regulation published in 2013. (2/22/18)