

## Report on Research Compliance Volume 20, Number 9. August 24, 2023 In This Month's E-News: September 2023

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By Theresa Defino

◆ **A criminology professor at Florida State University (FSU), dogged by accusations of research misconduct and the subject of multiple probes, was terminated last month, according to a letter published by *Retraction Watch*.** Hired in 2007, Eric Stewart received a notice of intent to terminate in March, which was the basis for the final action, James J. Clark, provost and executive vice president for academic affairs, wrote in the July 13 letter. Clark took issue with Stewart's "behavior and extreme negligence and incompetence that [he] demonstrated in the performance of [his] duties." Clark added that "decades of research that were once thought to be at the forefront" of criminology "contain numerous erroneous and false narratives."

Beginning in 2019, a coauthor of Stewart's raised concerns to FSU about "falsified data and findings;" six of Stewart's papers have since been retracted. However, FSU never conducted a formal research misconduct investigation into the allegations, stopping at the initial phase of three inquiries, according to *Retraction Watch*. The website also published, for the first time, internal documents it obtained in which Stewart "vehemently defended himself." However, Clark said Stewart's assignment of teaching research methods in light of the retractions did not comport with FSU's "mission to provide high quality education to students" and that he had not "demonstrated the ability to continue" conducting research. (8/17/23)

◆ **An NIH working group studying novel alternative methods (NAMs) to research involving animals must "emphasize in its final recommendations that animal models remain the premier method for numerous areas of research,"** according to a six-page comment letter from the Federation of American Societies for Experimental Biology (FASEB) to the agency. The letter responds to the working group's recent request for information. "Clarifying the research contexts in which NAMs may be appropriate and highlighting their role in *supplementing* work with animals is an important step in adjusting end-user and public expectations until validation strategies, metrics, and regulatory pathways become more defined," the letter said.

FASEB provided themes the working group should consider, including establishing "uniform validation guidelines and consider[ing] parallel investments in validation studies when funding NAMs to ensure new technologies are well-characterized with clear endpoints and metrics" and developing "and/or endors[ing] NAM-specific reporting and data-sharing guidelines that acknowledge the rigor, reproducibility, and translatability challenges inherent in non-animal models." Further, it said NIH should "strengthen partnerships and collaborations between federal agencies, industry, scientific societies, and animal researchers to exchange best practices, minimize regulatory burden, and ensure equitable and feasible implementation." (8/17/23)

◆ **The HHS Office for Human Research Protections (OHRP) and the University of Michigan are cosponsoring OHRP's annual community research forum, a two-day conference, Sept. 26-27, in Ann Arbor, Michigan.** Topics include how NIH's data management and sharing policy affects institutional review boards (IRBs) and human research protection programs, as well as "institutional approaches for operationalizing and ensuring compliance with this policy while supporting...researchers."

Also on the agenda is a discussion of "emerging artificial intelligence (AI) technologies and the ways that these

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technologies may be implemented in the context of human subjects research. Attendees will also explore how to evaluate the ethics of using AI technologies through contextual integrity to better guide regulatory oversight of these studies,” according to the meeting announcement. Other sessions will address community collaborations “from the perspective of a researcher and a community representative” and how community ethics review boards and IRBs can work together. (8/10/23)

◆ **The Monterrey Bay Aquarium Research Institute will repay \$2,891 for what National Science Foundation (NSF) Office of Inspector General auditors deemed “inappropriately allocated expenses.”** According to the Aug. 4 audit report, NSF awarded the institute a \$52.9 million mid-scale research infrastructure grant “to build and deploy 500 profiling floats to monitor ocean biology and chemistry.” As of September 2022, the institute received \$25,775,357 of that total. Auditors said the institute “reported approximately \$18.8 million in federal expenditures, with approximately \$10.6 million in expenditures on NSF direct and pass-through awards” for fiscal year 2021. (8/10/23)

◆ **The Association of American Medical Colleges (AAMC) is urging NIH to withdraw a recent “blanket policy change focused on foreign recipients regardless of the research being conducted” that the agency made to its Grant Policy Statement.** Instead, NIH should “consider policy updates which utilize existing agency mechanisms and employ a risk-based framework for increased reporting.” In a letter sent earlier this month, AAMC said NIH’s May 19 changes create “new, potentially conflicting requirements.” For example, NIH is “implementing a requirement that all foreign subrecipients regularly send grant awardees documents, lab notebooks, and research records, some of which are not typically collected by or required by a prime recipient. This change does not automatically lead to improvements in research oversight without considering the identity of the subawardee or the characteristics of the research,” AAMC said. The requirement for “subrecipients to provide copies of lab notebooks is incongruous with existing NIH policy and would substantially increase burden on researchers without improving award oversight,” AAMC added. (8/3/23)

◆ **An audit of approximately \$6.1 million of costs claimed by the Smithsonian Astrophysical Observatory (SAO) questioned \$2,496 for 15 video conferencing service licenses, among more than \$735,000 in tested transactions.** According to the auditors for the NSF Office of Inspector General, all Smithsonian Institution and SAO employees “already had access to licenses from the same video conferencing service during that period,” and thus, “it does not appear reasonable for SAO to have charged these costs to the NSF award. Further, SAO’s direct charging of these video conferencing costs does not appear consistent with its treatment of other costs it incurred for the same services.” (8/3/23)

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