

Report on Research Compliance Volume 20, Number 5. April 27, 2023 In This Month's E-News: May 2023

By Jane Anderson and Theresa Defino

◆ **NIH should conduct “site visits to foreign facilities that perform NIH-funded animal research” or require third-party verification to offer “reasonable assurance that award recipients’ annual self-reported project information is reliable and adequate to ensure the humane care and use of laboratory animals,”** according to a new report by the Government Accountability Office (GAO). Without such visits and other new steps, NIH may “miss opportunities to identify and respond to possible instances of noncompliance,” GAO said. NIH agreed with GAO’s recommendation, the only one contained in the report, and also said officials would provide an “action plan” to Congress. GAO noted that in fiscal years 2011 through 2021, NIH used grants or contracts “to obligate roughly \$2.2 billion to about 200 foreign institutions for approximately 1,300 projects involving foreign animal research.” Although funding came from 21 of NIH’s 27 institutes and centers, grants and contracts from three—the National Institute of Allergies and Infectious Diseases, National Cancer Institute and National Institute of Neurological Disorders and Strokes—collectively accounted for 52% of the total. Two-thirds went to research facilities in Canada, Australia and the United Kingdom.

When asked how often foreign institutions reported noncompliance during the 10-year period, NIH said there were four such instances, but none involved NIH-supported studies. Agency officials have never inspected any foreign research facilities conducting research it supports involving animals. The agency requires foreign institutions to certify compliance with international and local regulations and/or with the Public Health Service policy for the humane care and use of laboratory animals; unlike domestic awardees, NIH does not require institutional animal care and use committee “oversight of foreign facilities performing research for foreign award recipients.” However, in December, NIH proposed requiring foreign awardees to describe their oversight processes and annually indicate whether noncompliance was reported to the NIH Office of Laboratory Animal Welfare; the agency expected to finalize the new requirements this month, according to GAO. (4/20/23)

◆ **The HHS Office of the National Coordinator (ONC) for Health Information Technology issued a proposed rule that “builds on the monumental progress that has been made to support patients and providers across the care continuum,”** according to a blog post by Elise Sweeney Anthony, executive director of the ONC Office of Policy.

Published April 18 with a comment deadline of June 20, provisions in the proposed rule address “the movement of health information electronically” and focus on “new data standards that help ensure that information can be understood when it enters and leaves a system, on electronic case reporting that supports public health and emergency response across the country, and on algorithm transparency so that health IT users have more information about the algorithms enabled by or interfacing with the certified technology they use for care,” Anthony wrote. She added that ONC will hold four webinars to discuss various aspects of the rule. (4/20/23)

◆ **The HHS Office of Research Integrity (ORI) concluded that a former assistant professor of medicine at Yale University engaged in research misconduct in research supported by U.S. Public Health Service funds.** ORI found that Carlo Spirli, who had worked in Yale’s Department of Digestive Diseases, “engaged in research misconduct by knowingly, intentionally, or recklessly falsifying and/or fabricating data” included in four published papers, two presentations and three grant applications. The data involved “falsified and/or fabricated Western blot image data for cholangiopathies in a murine model of Congenital Hepatic Fibrosis.” According to ORI, Spirli

reused blot images, with or without manipulating them to conceal their similarities, and falsely relabeled them as data representing different experiments or proteins. Spirli falsified quantitative data in associated graphs purportedly derived from those images in 21 figures included in the papers, presentations and grant applications.

The papers in question all were published in the journal *Hepatology* between 2012 and 2015, while the presentations occurred at meetings of the European Association for the Study of the Liver in 2011 and the American Association for the Study of Liver Diseases in 2012. Two of the grant applications were submitted in 2010, and one was submitted in 2018. All have been administratively withdrawn by the funding agency. Spirli has entered into a four-year voluntary exclusion agreement with government agencies and will request that three of the four papers be corrected or retracted. (4/13/23)

◆ **The National Science Foundation (NSF) Office of Inspector General (OIG) concluded following an audit that several improvements are needed in NSF's Graduate Research Fellowship Program (GRFP).** Specifically, OIG said NSF did not always ensure that all GRFP reporting and participation requirements were consistently enforced, and NSF did not always supply the information or guidance institutions needed to properly manage awards. "This occurred, in part, because NSF did not have sufficient standard operating procedures for the GRFP or adequately train GRFP staff," the auditors said. "In addition, NSF had insufficient information technology controls to determine award amounts and ensure awards were made only in support of eligible fellows." OIG found that, between 2010 and 2019, "NSF awarded approximately \$824,231 in GRFP funding to institutions in support of fellows the institutions reported had exceeded program limits for time," cost of education allowance and stipend. In addition, the report said that between 2012 and 2019, "NSF awarded more than \$1.2 million to institutions in support of fellows the institutions reported had made unsatisfactory progress or did not submit required activity reports."

The OIG report recommended six specific actions to improve the GRFP, and NSF agreed with all six recommendations. NSF already has begun addressing some of these areas, OIG said. For example, it has focused on hiring program leadership and additional staff to oversee GRFP, the report said. NSF also has obtained contractor support to document its existing processes, is revising its Administrative Guide, and is improving its IT controls, the report said. (4/13/23)

◆ **NSF has issued newly revised questions and answers on how to prepare proposals and administer awards.** The 19-page document, "Frequently Asked Questions (FAQs) On Proposal Preparation and Award Administration Related to the NSF *Proposal & Award Policies & Procedures Guide* (PAPPG)," includes alphabetical questions on topics ranging from "Assistance Listings (formerly (CFDA Numbers))" to "Uniform Resource Locators (URLs)."

Several FAQs noted that changes are coming to NSF's PAPPG requirements. For example, under "Biographical Sketches," the document states that "the mandate to use SciENcv only for preparation of the Biographical Sketch will go into effect for new proposals submitted or due on or after October 23, 2023. In the interim, proposers may continue to prepare and submit this document via use of SciENcv or use the NSF fillable PDF. NSF, however, encourages the community to use SciENcv prior to the October 2023 implementation." Similarly, under "Responsible and Ethical Conduct of Research (RECR)," the document notes that requirements "to have a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to faculty and other senior personnel who will be supported by NSF to conduct research will go into effect for new proposals submitted or due on or after July 31, 2023. NSF, however, encourages the community to establish such training and oversight for faculty and other senior personnel prior to the July 31, 2023, implementation." (4/6/23)

◆ **The Council on Governmental Relations has published a new report discussing both personal financial and institutional conflict of interest issues where they most commonly occur, including consulting, licensing, and clinical studies.** The report, "Analyzing Personal Financial and Institutional Conflicts of Interest in Academic

Research Contexts,” also addresses federal research funding agencies’ recent focus on the intersection of conflicts and malign foreign influence, including a discussion of recent agency efforts to recast conflicts of commitment as “non-financial conflicts of interest.”

The document is designed to assist research administrators, academic officers, and faculty members in identifying, analyzing, and developing strategies for addressing different types of conflicts of interest in the context of federally grant-funded research. The paper, which results from the efforts of a working group assembled by COGR’s Research Ethics and Compliance Committee, includes key regulations and guidance documents, points institutions should consider in evaluating scenarios, and case studies that can be used to foster discussion and support educational efforts. (4/6/23)

◆ **Allegations of traditional research misconduct and professional misconduct “rose precipitously” over the past five years**, Mike Lauer, NIH deputy director for extramural research, said in releasing new data on total research integrity allegations and NIH’s efforts to identify and address integrity issues. In his *Open Mike* blog, Lauer said that NIH “generally handled an average of 100 violations each year up to around 2017.” However, the number of violations jumped to 342 in 2018 and rose even further to 549 in 2019, 531 in 2020, 573 in 2021 and 564 in 2022.

“Our integrity portfolio broadened greatly around 2018 as professional misconduct became a major focus along with traditional scientific misconduct,” Lauer said. “Importantly, we also made concerted efforts with the research community over recent years to identify and address integrity issues.” Specifically, allegations of research misconduct—fabrication, falsification and plagiarism—were generally less than 100 per year; however, the numbers started rising in 2019, Lauer said, possibly because of NIH’s reminder in late 2018 that recipients should notify NIH when they identify or suspect research misconduct that impacts or may impact an NIH-supported project. Alleged violations of peer review rules also rose around tenfold between 2013 and 2022, he said, commensurate with “many reminders” to the research community about rules and violations. (3/29/23)

◆ **After reviewing \$1.7 million in expenses claimed by Rensselaer Polytechnic Institute (RPI) for the period between Sept. 9, 2018, and Sept. 10, 2021, auditors for the NSF OIG questioned \$198,137 of costs, \$116,664 of which was for a service agreement that OIG said was unallowable because it did not benefit the NSF award.** In addition, the OIG report said RPI used \$54,492 of participant support funding awarded on two NSF awards to cover nonparticipant expenses, which is not allowable without prior NSF approval. Some of that funding was used to cover faculty summer salaries, employee benefits, overhead and other nonparticipant-related expenses, the OIG report said. In addition, RPI used participant support costs to cover housing, meals and indirect expenses at a conference, even though the grants officer rejected the request to rebudget the participant support costs, the report said.

RPI also incurred some unallowable publication expenses, the OIG said. “RPI charged two NSF awards for \$5,255 in expenses incurred to publish research articles that did not acknowledge the NSF awards charged, as required for the publication expenses to be allowable per federal regulations and NSF PAPPs [Proposal and Award Policies and Procedures Guides],” the report said. Finally, RPI charged two NSF awards for travel expenses that were either unreasonable or did not benefit the awards charged, the report said. The auditors included six findings and one area for improvement in the report, with associated recommendations for NSF to resolve the questioned costs and ensure RPI strengthens its administrative and management controls. RPI agreed with the majority of the findings in the report and agreed to reimburse NSF for \$167,254 in questioned costs. (3/29/23)

This publication is only available to subscribers. To view all documents, please log in or purchase access.

[Purchase Login](#)