

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

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♦ 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.

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