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OLAW Recounts Progress Fulfilling Requirements Under the Cures Act

By Jane Anderson

The NIH Office of Laboratory Animal Welfare (OLAW) has taken significant steps over the past several years to streamline regulations and reduce administrative burden for institutions that conduct research involving animals as a result of the 21st Century Cures Act, the agency's leader said.

The changes, required by provisions in the legislation, touch on reporting periods, inspections, congruence review and other administrative requirements, and are intended to lessen the paperwork for research institutions, OLAW Director Patricia Brown said during a recent webinar.^[1]

The U.S. Department of Agriculture (USDA) also is making administrative changes because of the act, Elizabeth Theodorson, assistant deputy administrator of animal care at the USDA Animal and Plant Health Inspection Service, told attendees.^[2]

The 21st Century Cures Act, comprehensive bipartisan legislation approved in 2016, is intended to advance biomedical research and clinical trials and streamline the drug approval process, Brown said. The legislation, which assigns NIH as the lead agency in cooperation with USDA and the Food and Drug Administration (FDA) to focus on animal care and use in research, also mandates federal efforts to reduce the administrative burden for researchers, she said.

Specifically, Brown said, the legislation states in Section 2034 that the NIH, USDA and FDA will complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce the administrative burden on investigators while maintaining the integrity and credibility of research findings and the protection of research animals.

Following passage of the legislation, NIH convened a working group in early 2017, and "began their effort by reviewing relevant regulations and policies," Brown said. In 2018, the agencies held listening sessions and asked the public to provide their ideas for how to meet the requirements of the law. They then released a request for information (RFI) for public comment on the proposed actions to "improve the coordination and harmonization of the regulations and policies," Brown said. That working group issued a draft report in December 2018 and a final report in August 2019 that incorporated public comment feedback. Since then, OLAW has issued multiple additional RFIs and final guidance on four topics, Brown said.

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