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Agencies Preview Cures Act Guidance Documents, Rules for Animal Research

By Theresa Defino

Four years after the Cures Act[1] was signed into law, three agencies with oversight of animal care and use programs and research involving animals report making progress complying with a requirement to reduce administrative burdens. Updated policy guidance, regulations and other resources are in the works, according to agency officials, although they offered few specifics as to timing.

In a December 2019 webinar, representatives from the NIH Office of Laboratory Animal Welfare (OLAW), U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) discussed Cures Act implementation.[2] Officials from the same agencies revisited the Cures Act during a new webinar OLAW held March 11.[3]

OLAW Director Patricia Brown began by reviewing that Section 2034 of the act called for a focus on reducing administrative burden in animal research, placed NIH as the lead agency to work with the FDA and USDA, and established time frames for certain efforts. As Brown noted, among the goals of the law are to advance biomedical research but also to "streamline the drug and device approval process to bring treatments to patients faster."

The agencies met the requirement to "complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals," Brown said. NIH created a working group in 2017, and members presented their recommendations in March 2018 along with a request for information (RFI) that was followed by a draft report in December and a final report in August 2019, she noted.

The Cures Act also "requires that the agencies improve coordination of regulations and policies," Brown said. She pointed out several examples of achievements in this regard. The deadline for the annual report to both USDA and OLAW is now Dec. 1 of each year, she said. OLAW has also adopted a 60-day comment period minimum for "proposed policies and guidance changes."

OLAW Expects Host of Guidance Documents

OLAW issued three RFIs last year, which addressed flexibilities for semiannual animal facility inspections,[4] grant-to-protocol congruency,[5] and use of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) program description for the assurance required by OLAW.[6]

Brown said she expected "final guidance on all three of these policies" to be issued this spring. OLAW is also working on a number of potential guidance documents that have not yet been released for comment.

These are "proposed guidance and resources" on "topics that were identified for NIH action in the report," she

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said.

- Expanded use of designated member review for protocol review of low-risk activities.
- Use of veterinary verification consultation for significant changes to approved protocols.
- Activities that are exempt from institutional animal care and use committee (IACUC) review.
- IACUC options for review of nonpharmaceutical-grade substances.
- Required reporting of noncompliance to OLAW, including what to report, "what not to report, and what to include in the report."
- IACUCs' responsibility to report departures from *The Guide for the Care and Use of Laboratory Animals* to the institutional official as part of a semiannual IO report.
- Public Health Service (PHS) policy applicability to zebra fish "immediately after hatching."

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