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Report on Reducing Burdens in Animal Research Offers Changes, Concessions

By Theresa Defino

Several times in the new draft report on reducing burdens in animal research, the NIH Office of Laboratory Animal Welfare (OLAW) said it “does not support this approach.”

One is in reference to a suggestion about abandoning occupational health and safety programs; two others relate to dispensing with reliance on the National Academy of Sciences (NAS) *Guide for the Care and Use of Laboratory Animals*.

OLAW also pushed back against a comment that it seek a change through Congress to revise the requirement for semiannual inspections and program reviews to “at least annual.” Such a change “would negatively impact animal welfare,” OLAW said, and, citing the same reason, it also turned down a related recommendation to permit “agents” of an institutional animal care and use committee (IACUC) to conduct inspections.

Nearly 20,000 Comments Were Received

But in other respects, research compliance officials and investigators who work with animals may find a fair amount worth cheering in the 59-page report, “Reducing Administrative Burden for Researchers: Animal Care and Use,” which is open for comment until Feb. 5. At a minimum, OLAW and other agencies involved may rate an “A” for earnestness.

OLAW, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) released the draft report for comment on Dec. 7 in the form of a request for information.

Aided by a working group, agency representatives sifted through, analyzed and categorized more than 19,000 comments submitted when input was sought earlier this year. The formal comment period was preceded by a listening session the agencies held in January at the conclusion of a Federal Demonstration Partnership meeting (*RRC 2/18, p. 3*).

The report was required by the 21st Century Cures Act, which requested that the agencies “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.”

Although the report is still in a draft form, the agencies may technically have met the deadline set by Congress. The law required the review to be finished within two years of the Cures Act becoming law, which happened on Dec. 13, 2016.

“The draft report outlines areas in which we can make oversight more efficient and reduce burden without compromising animal welfare or scientific integrity: these areas include institutional animal care and use committee inspections, protocol reviews, and annual progress reporting. The draft report recommends increased

coordination across federal agencies by refining guidance on federal standards and harmonizing agency requirements, training, and resources,” Michael Lauer, NIH deputy director for extramural research, wrote on his “Open Mike” blog.

Encouraging feedback from “scientists, research institutions, animal welfare advocacy groups, professional societies, and the public,” Lauer promised that OLAW, “with our federal partners, we will continue to identify redundancies in federal requirements and to harmonize policies which affect laboratory animal welfare. Moreover, we will continue to provide federal oversight to ensure that when animal research is necessary, the animals are responsibly cared for and humanely used in federally funded studies.”

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