Updates from the 7th Q&A with the USDA

A recap from the latest webinar addressing Standard Operating Procedures, annual reports, and animals in clinical trials

B. Taylor Bennett and Matthew R. Bailey

At a recent webinar hosted by the National Association for Biomedical Research (NABR), "Q&A With the USDA: The Seventh Edition," Drs. Betty Goldentyer and Cody Yager of the United States Department of Agriculture (USDA) Animal Plant and Health Inspection Service (APHIS) Animal Care (AC) addressed questions submitted by participants. This article will summarize their responses concerning the IACUC's role and responsibility for approving Standard Operating Procedures (SOPs), several issues involving completion of the annual report, and animals involved in clinical trials.

SOPs & IACUCs

One question addressed the USDA's expectations for an IACUC to review SOPs and policies relating to the animal care and use program. Specifically, what language in the regulations requires the IACUC to review these documents?

The USDA representatives referred to Section 2.31 (c)(1) of the Animal Welfare Regulations (AWR), which requires the IACUC to "review, at least once every six months, the research facility's program for humane care and use of animals using Title 9, Chapter 1, Subchapter A - Animal Welfare as a basis for evaluation[1]."

The USDA leaves it up to the IACUC to decide how to conduct that review, and during inspections the agency looks for how the IACUC handles new SOPs and policies as well as its process for continuing review or making changes to those documents. New or updated SOPs that are used as part of the protocol review process should be reviewed in full and approved by the IACUC. For those SOPs that deal with administrative, husbandry, or veterinary care issues, IACUC approval is not required but the IACUC should be kept informed when new procedures are developed and when existing ones either undergo a regular review or are changed. This could be done with an administrative report that highlights what took place.

Completing your annual report

What should be reported in Column E on the annual report? Only what is described in the AWR and on the annual report form itself. This column is limited to protocols that involve accompanying pain or distress to the animals for which the use of appropriate anesthetic, analgesic or tranquilizing drugs would adversely affect the procedure, results or interpretation. This is a very specific set of animals. Preparers should not include breakthrough pain despite analgesics; food/water restriction managed so as to avoid pain or distress; unexpected death; or any clinical, management or colony care issues.

For any animals to which Column E does apply, an explanation must be attached to the report. This should be brief, explained in plain terms, and focused on what the animal experienced (for example: seizures, neurologic signs, inappetence, lethargy, gastrointestinal distress, etc.). The reasons pain and distress could not be relieved should be science-based and described clearly in plain terms (any procedures that limit pain or distress in Column E animals could also be described here). If pain or distress could not be relieved due to regulatory requirements, the preparer of the report should list the agency, the code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113.102). If the requirement is in accordance with a guidance document, such as an agency notice or harmonization guideline, the preparer should provide sufficient information to identify the cited document.

The USDA representatives also provided an update on the status of the electronic submission process for the 2019 Annual Report. The USDA is currently implementing eAuth "the Next Generation." This, the representatives say, will make it easier to gain initial access to the online system while still ensuring the documents are secure. Those who were eAuthenticated last year are already in the system and can sign in to complete this year's report; new users can register at https://www.eauth.usda.gov/eauth/b/usda/login.

The system has two additional features this year as well. A certification statement has been added so that when the Institutional Officer (IO) or CEO has reviewed the report, the preparer will be able to check a box accordingly and submit the report; the IO/CEO does not need to be eAuthenticated. Also this year, once a facility contact person is in the system, they will be able to set up their facility's contact list and designate who will have access to the report as it is completed and submitted.

Use of animals in clinical trials

There was also a question concerning animals used in clinical trials. The USDA clarified that the participation of animals in clinical trials in the context of medical care under a veterinary-client relationship is not covered by US regulations, does not require IACUC approval, and should NOT be reported on the annual report.

In this article we summarized the responses of the USDA representatives to several questions submitted for a recent NABR webinar. We selected these questions because they either have been asked and answered in the past or afforded an opportunity to address changes within Animal Care's processes and procedures. It is important that those who are responsible for animal care and use programs have a thorough understanding of what is required by the regulations and the processes and procedures used to implement them. ❐

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References

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