

## A WORD FROM USDA AND OLAW

In response to the issues posed in this scenario, the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) and the National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW) provide the following clarifications.

In this scenario, a veterinary resident found a cat abandoned on the premises of the veterinary school and placed it on a clinical trial to study a new cardiomyopathy treatment without the facility's or the principal investigator's knowledge. The resident also implemented a treatment regimen that was not in accordance with the protocol of the clinical trial and left the animal housed in its original carrier overnight.

**Response from USDA-APHIS**

Under the AWA regulations, a research facility that obtains dogs and cats from sources other than dealers, exhibitors, and exempt persons shall hold the animal for 5 full days, which does not include the day of acquisition and the time in transit before use in the facility<sup>1</sup>. In addition, research facilities are required to create and maintain accurate acquisition and disposition records on dogs and cats<sup>2</sup>. In this scenario, the resident should have informed the facility of the abandoned animal so the date of acquisition could be recorded and the 5 day holding period implemented. The holding period is especially important in this scenario because there was no verification of abandonment. If the cat remained unclaimed after holding, it would become property of the institution and therefore receive an official USDA tag or tattoo in accordance with the regulations<sup>3</sup>. Placing the animal on study without implementing a holding period is out of compliance with the regulatory requirements. In addition, leaving the cat in the carrier overnight, when the cat is not in transit, is not in compliance with the regulatory requirements for primary enclosures<sup>4</sup>.

After review and investigation of the concerns involving the care of this animal and the conduct of this activity, the IACUC must determine the appropriate actions to correct the non-compliance and prevent further recurrence. Reporting the action to USDA is required if the IACUC elects to suspend the activity.

**Response from NIH-OLAW**

Institutions must implement the PHS Policy for all activities involving animals

supported by Department of Health and Human Services (HHS) agencies and must ensure that other activities with animals do not affect or pose risks to PHS supported activities<sup>5</sup>. In addition to HHS agencies, the National Science Foundation (NSF), the Department of Veterans Affairs (DVA) and the National Aeronautics and Space Administration (NASA) have agreements for OLAW to provide oversight of their funded activities involving animals.

In this incident, the clinical trial is not federally funded. However, the behavior of the resident indicates a serious programmatic training failure at the veterinary school and is thus reportable to OLAW<sup>6</sup>. Under the Memorandum of Understanding between NIH and USDA, OLAW would inform the USDA of the reported noncompliance related to cats, whether the activity is covered under the AWA regulations or not<sup>7</sup>. The suspension by the IACUC of an individual's privileges to conduct animal research is not always reportable to OLAW. It is reportable if the reason for the suspension involves serious noncompliance<sup>6</sup>. If in doubt about whether an incident must be reported, institutions are encouraged to contact OLAW to discuss the details and receive guidance on what and whether to report. □

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**References**

- Title 9 Chapter 1 § 2.38 (j) – Holding period
- Title 9 Chapter 1 § 2.35 (d) (1-2) – Recordkeeping requirements
- Title 9 Chapter 1 § 2.38 (g) – Identification of dogs and cats
- Title 9 Chapter 1 § 3.6 – Primary Enclosures
- National Institutes of Health. *Public Health Service Policy on Humane Care and Use of Laboratory Animals - Frequently Asked Questions. Institutional Reporting to OLAW, Question C.2* (US Department of Health and Human Services, Bethesda, MD, USA, revised 2017). [online] <https://olaw.nih.gov/guidance/faqs#586>
- National Institutes of Health. *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*. Notice NOT-OD-05-034 [online]. (National Institutes of Health, Bethesda, MD, 24 February 2005). <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>
- MOU Among USDA/FDA/NIH*. FDA MOU 225-16-010, APHIS Agreement No. 11-6100-0027-MU, 29 April 2016. [online] <https://olaw.nih.gov/guidance/finalmou.htm>

case, the cat was found abandoned outside the clinic so a holding period of 5 full days is required before it can be used. Also, holding the animal overnight in a crate likely violated the standards for a primary enclosure, including providing adequate floor space and resting surfaces.<sup>2</sup> These deficiencies should be discussed by the IACUC and included in the minutes and the semiannual evaluation report to the Institutional Official.

From the scenario presented, it is clear that the administration of the two drugs together was not an approved activity. The IACUC should also determine if any other protocol noncompliance occurred. Questions to consider include: 1) was the cat properly enrolled in the study? 2) Was a physical exam performed and documented to determine the animal's general health and presence of cardiomyopathy? 3) Was this a trained resident acting irresponsibly, or did the PI fail to provide sufficient training and oversight? Based on the findings of the investigation, the IACUC actions may focus on the resident, the PI and all study personnel, and their future conduct of the protocol. At a minimum, the resident should not be allowed further participation on this protocol, until the IACUC has completed their investigation, and the PI should ensure that the protocol is being followed as approved.

The actions of this resident are concerning and should be brought to the attention of the director of his/her residency program. If the resident is paid with funds from a PHS training grant or other educational stipend from federal funds, the incident may need to be brought to the attention of the institutional grants department. □

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- Public Health Service. *PHS Policy on Humane Care Use of Laboratory Animals*. (U.S. Department of Health and Human Services, National Institutes of Health, Bethesda, MD 2015).
- Animal Welfare Act. Public Law 89-544, 1966, as amended (P.L., 91-579, P.L. 94-279, and P.L. 99-198), 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9 Chapter 1, Subchapter A, Parts 1,2 and 3.