Not a suspension, but still reportable

As illustrated in this scenario, surgery and anesthesia of animals, even when performed by trained individuals, carries the risk of complications resulting in morbidity and mortality. OLAW acknowledges this reality in guidance NOT-OD-05-034:

“there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide*”¹.

The *Guide for the Care and Use of Laboratory Animals*² states that effective post approval monitoring (PAM) strategies include “regular review of adverse or unexpected experimental outcomes affecting the animals”. These strategies help fulfill the Health Research Extension Act and the Animal Welfare Act requirement that the IACUC inspect animal care and use facilities, including sites used for animal surgeries, every 6 months. Further, the *Guide* recommends a monitoring program that supports a culture of care focusing on the animals’ well-being as well as encourages an educational partnership with investigators. After the dog died, the PI, veterinarians, and IACUC fulfilled best practices and regulatory requirements for PAM by voluntarily halting the study pending full investigation of this adverse event.

According to the Animal Welfare Act (AWR 2.31(d)(6))³ and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (IV.C.6)⁴, a suspension of activity can occur only after review of the matter at a convened meeting of a quorum of the IACUC and a majority vote of the quorum to suspend. The immediate and voluntary halt of the study by the PI pending further investigation of the adverse event does not meet the criteria for suspension. In addition, the investigation identified no regulatory noncompliance, but rather an equipment issue that occurred despite timely preventive maintenance. While these conclusions do not support reporting, NOT-OD-05-034 does contain one example of reportable situations that could be interpreted to fit this event: “conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and *mechanical failures*, resulting in actual harm or death to animals”. Therefore, the IACUC should report the event to OLAW. The OLAC report and IACUC meeting minutes should detail the investigation summary, measures taken to address the finding and any additional preventive measures taken.

Additional preventive measures include follow-up communication with the vaporizer company to ensure adequate training for all technicians servicing the units. Measures should also address the question of whether the veterinary technician felt constrained by the protocol to maintain a vaporizer setting that resulted in too deep a plane of anesthesia. Assuming necropsy did not identify any underlying

A WORD FROM APHIS AND OLAW

In response to the issues posed in this scenario, the US 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 dog unexpectedly dies while undergoing an experimental cardiac surgical procedure and the institution’s IACUC must decide if the incident is reportable to USDA and NIH.

USDA-APHIS response

The issue in this scenario is whether the research facility is obligated to report to USDA an event involving a dog that died unexpectedly while undergoing an experimental cardiac surgical procedure.

There are four items research facilities are required to report to APHIS under the Animal Welfare Act (AWA) regulations: an annual report on animal usage¹, a change of operation affecting its status as a research facility², an animal activity suspension by the IACUC during a convened meeting with a quorum present³, and a failure to correct a significant deficiency identified by the IACUC during a semiannual inspection⁴. Here, the investigator voluntarily halted the study following the animal’s death to allow for review. The review determined that the veterinary technician followed the approved protocol for anesthetizing the animal, and that a properly serviced anesthetic vaporizer machine malfunctioned, leading to the animal’s death. Although there was some question about whether the veterinary technician independently monitored the animal’s depth of anesthesia beyond relying on the machine’s reported levels, under these circumstances, there is not a regulatory obligation to report the event.

However, a facility may elect to voluntarily report an incident to USDA. Voluntary reporting allows proactive identification, correction, and prevention of issues that may negatively impact animal welfare, and provides an opportunity for a

research facility to keep its USDA inspector up-to-date on activities at the facility.

NIH-OLAW response

The IACUC conducted an investigation of the incident and found that the surgical procedures, anesthetic monitoring, and routine maintenance of the anesthetic equipment were all appropriate. They determined that the cause of death was due to a faulty anesthetic vaporizer. Adverse events such as this where an animal is harmed or dies as the result of equipment malfunction are considered reportable to OLAW⁵. If institutions with an OLAW-approved Animal Welfare Assurance are in doubt about whether an incident is reportable, OLAW encourages a preliminary call from an authorized institutional representative and will provide guidance on the specific circumstances. The incident does not meet the requirements for a suspension because Public Health Service Policy (IV.C.6) states that: “The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present”⁶. □

Patricia Brown¹ and Bernadette Juarez²

¹Director, OLAW, OER, OD, NIH, HHS, Bethesda, MD, United States. ²Deputy Administrator, Animal Care, APHIS, USDA, Washington, DC, United States. e-mail: brownp@mail.nih.gov; bernadette.r.juarez@aphis.usda.gov

Published online: 22 July 2019
<https://doi.org/10.1038/s41684-019-0357-z>

References

1. Title 9 Chapter 1 Subchapter A § 2.36.
2. Title 9 Chapter 1 Subchapter A § 2.30(c).
3. Title 9 Chapter 1 Subchapter A § 2.31(d)(7).
4. Title 9 Chapter 1 Subchapter A § 2.31 (c)(3).
5. National Institutes of Health, Office of Laboratory Animal Welfare. Guidance on Prompt Reporting to OLAW Under the PHS Policy on Humane Care and Use of Laboratory Animals (2005). <https://grants.nih.gov/grants/guide/notice-files/not-od-05-034.html>
6. Office of Laboratory Animal Welfare, National Institutes of Health. Public Health Service Policy on Humane Care and Use of Laboratory Animals. (US Department of Health and Human Services, Bethesda, Maryland, USA, 2015). <https://olaw.nih.gov/policies-laws/phs-policy.htm>