



UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE USDA OFFICIAL WARNING NOTICE OF ALLEGED VIOLATION	CASE NUMBER: MA240010-AC
	ALLEGED VIOLATOR: University of Massachusetts Medical School
	ADDRESS (City, State, ZIP Code): Worcester, MA 01655
The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws: Date of Alleged Violation: February 3, 2024 through February 7, 2024 9 C.F.R. § 2.33(b)(2) Attending veterinarian and adequate veterinary care. Each research facility shall establish and maintain programs of adequate veterinary care that include (2) the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. You failed to ensure adequate veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries. As documented on the February 27, 2024 inspection report, APHIS Officials reviewed records pertaining to Institutional Animal Care and Use Committee (IACUC) approved Protocol 028, including the proposal for animal use and medical records for a pig on the study. (Pig No. 726). Protocol 028 states the MI model animals are “generally stable throughout the study”. The protocol describes several postoperative conditions and parameters that were “rare” or “very rare” including loss of appetite, dehydration, and signs of heart failure. On February 3, 2024 and February 5, 2024, entries made by veterinary and laboratory staff for the record of Pig No. 726 noted that the animal was lying down, lethargic, not finishing food, and was offered a special dietary product or fruit to entice it to eat. On February 6, 2024, prior to a scheduled non-invasive study procedure, the morning entries in the record state that the pig was lethargic and had “peripheral cyanosis.” Despite the noted condition of the animal, laboratory staff administered the injectable anesthetic and performed the noninvasive procedure as planned. On February 6, 2024, staff returned the pig to its enclosure and recorded the last entry at 1410. A review of the record failed to identify additional monitoring of the animal’s condition after it was returned to its enclosure.	



On the morning of February 7, 2024, entries made by veterinary staff for the record of Pig No. 726 noted that the pig was “lateral, cyanotic extremities” and that the pig tried to stand up twice but then fell on its side each time. Veterinary staff contacted laboratory staff to inform them of the animal’s symptoms. At 10:15 a.m. on that same day, a veterinarian assessed the animal and found that the pig was recumbent, with pale mucus membranes, and cyanotic legs and ears. Following the assessment, the veterinarian prescribed the administration of a dose of the analgesic buprenorphine to be repeated at 3 p.m. that day. At 12:08 p.m. the pig died. Necropsy results revealed infection in the tissues of the neck and in the heart of the pig.

Date of Alleged Violation: February 3, 2024 through February 7, 2024

9 C.F.R. § 2.33(b)(3) Attending veterinarian and adequate veterinary care. Each research facility shall establish and maintain programs of adequate veterinary care that include (3) daily observation of all animals to assess their health and well-being. That daily observation of animals may be accomplished by someone other than the attending veterinarian, provided that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

You failed to ensure a mechanism of direct and frequent communication so that timely and accurate information on animal health and well-being was conveyed to the attending veterinarian.

As documented on the February 27, 2024 inspection report, APHIS Officials reviewed records pertaining to Institutional Animal Care and Use Committee (IACUC) approved Protocol 028, including the proposal for animal use and medical records for a pig on the study. (Pig No. 726). Protocol 028 states the MI model animals are “generally stable throughout the study”. The protocol describes several postoperative conditions and parameters that were “rare” or “very rare” including loss of appetite, dehydration, and signs of heart failure.

In the following instances, veterinary and laboratory staff failed to contact the Attending Veterinarian to communicate issues of animal health observed postoperatively:

1. On February 2, 2024, several entries in the animal’s record by veterinary and laboratory staff that noted a decreased interest in food following a study procedure. On February 3, 2024 and February 5, 2024, staff noted that the animal was lying down, lethargic, not finishing food, and was offered a special dietary product or fruit to entice it to eat. On the morning of February 6, 2024, entries in the animal’s record identified that the pig was lethargic with “peripheral cyanosis.” As part of the approved protocol, on that same day, laboratory staff administered an injectable anesthetic and performed a second IACUC approved procedure. A review of the records failed to find

that before moving forward with the second IACUC procedure, facility staff contacted the Attending Veterinarian to communicate the animal's health.

2. On February 6, 2024, at the conclusion of the IACUC approved procedure, laboratory staff placed an intravenous catheter into Pig No. 726 and administered an inhalant anesthesia agent for a "Fluid Replacement" procedure. This procedure is not described in the IACUC approved protocol. A review of the records failed to identify that, prior to the procedure, the Attending Veterinarian was contacted to communicate the changes in the animal's health. Additionally, the Attending Veterinarian was not contacted prior to administering the inhalant anesthesia agent, placing the intravenous catheter, and prior to performing the "Fluid Replacement" procedure on the animal.

Date of Alleged Violation: August 13, 2024

9 C.F.R. § 2.31(d)(1)(ii) IACUC review of activities involving animals. In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing. Provided, however, that field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

You failed to ensure the IACUC determined that for proposed activities the principal investigator considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and provide a written narrative description of the methods and sources used to determine that alternatives were not available.

IACUC approved Protocol Nos. 0020, 0028, and 0084 did not provide a written narrative description of the methods and sources used to determine that alternatives were not available to a procedure that may cause more than momentary pain or distress to the animals that are included in each of the protocols (vascular cutdown).



The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue sanctions, which may include criminal prosecution, for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

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Director, Investigative and Enforcement Services

DATE ISSUED:

7/3/2025

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