

Virginia Polytechnic Institute & State University 300 Turner Street, N.W., Suite 4120 Blacksburg, VA 24061

SETTLEMENT AGREEMENT

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

Date of Alleged Violation: February 4, 2021

9 C.F.R. § 2.38(f)(1) Handling.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

Virginia Polytechnic Institute & State University (VATECH) failed to handle animals as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

On February 4, 2021, the Principal Investigator (Pl) and lab staff on protocol 20-100 used six Gottingen pigs in a study involving traumatic brain injuries. The first pig used during the procedure died. Staff noted blood on the intubation tube. The staff made positioning changes for the second pig that also died with "more blood" noted. The Pl team continued to troubleshoot and change the study procedures. Two of the six pigs used in the study survived, but exhibited abnormal neurological signs.

At no point during the six procedures was the attending veterinarian notified of the adverse events occurring. Following anesthetic recovery of the surviving pigs, a veterinarian's assessment of their neurologic signs included ataxia (incoordination), weakness in all four limbs, mild/moderate mental depression, and one pig noted with trembling. The veterinarian prescribed pain medication for both pigs.

Continuing the study with the manipulations and handling of the pigs after the initial unexpected death led to potentially preventable deaths and pain for the surviving pigs. The PI reported the incident to the IACUC on February 18, 2021.

Date of Alleged Violation: June 29, 2021

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AC

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9 C.F.R. § 2.38(f)(1) Handling.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

VATECH failed to handle animals as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

During a routine inspection, APHIS officials observed an overweight black and white dairy cow (Ear Tag #5483) from the veterinary teaching herd lying sternal close to the fence/gate leading to the covered student palpation stalls. The cow had a respiratory rate of 88 breaths per minute (normal 10-30) and exhibited flaring of the nostrils. When the dairy caretaker got her to stand, she stood with her neck extended, breathing heavily, nostrils flaring, and a respiratory rate of 100 breaths per minute.

A large animal veterinarian examined the cow and diagnosed her with heat stress due to the warm temperature, high humidity, and being overweight. Access to shade appeared to improve her condition enough that she was able to return to her pasture that day.

Natural shade and shelter areas (trees) were available for the cows, but were far away, down a hill, across parts of two pastures, and up another hill.

Date of Alleged Violation: Between March 3, 2022 – March 8, 2022 9 C.F.R. § 3.129(a) Feeding.

The food shall be wholesome, palatable, and free from contamination and of sufficient quantity and nutritive value to maintain all animals in good health. The diet shall be prepared with consideration for the age, species, condition, size, and type of the animal. Animals shall be fed at least once a day except as dictated by hibernation, veterinary treatment, normal fasts, or other professionally accepted practices.

VATECH failed to provide food of sufficient quantity and nutritive value to maintain all animals in good health.

During a routine inspection, APHIS officials reviewed the necropsy report of a six-day-old piglet that died from starvation and emaciation due to the facility's failure to ensure it received a sufficient amount of food to maintain proper body condition and health after removing the piglet from its mother for a research protocol.

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Several attempts were made to teach the pig to drink from a bowl, such as by dipping its snout into the milk and using fingers to try to lure the piglet to the bowl however, the facility's notes indicate that the piglet did not learn to eat from the bowl.

Although the facility made several unsuccessful attempts to teach the piglet self-feeding, the facility did not ensure the animal received sufficient feed through an alternate means (bottle, syringe, or other method) to maintain proper body condition and health. In addition, the volumes of supplemental milk occasionally offered by syringe feeding over each 24-hour period were approximately ten percent of the animal's daily energy requirements.

The facility failed to take the necessary steps to ensure that the piglet received a sufficient quantity of food in a manner that considered its age, condition, and inability to self-feed from a bowl. There were no additional steps implemented such as calculating nutritional needs to maintain body weight, increasing the food offered via syringe or other method, measuring glucose levels, measuring hydration levels and/or fluid intake, or conducting weight checks.

On the afternoon of March 8, 2022, staff found the pig dead. The necropsy reported that the pig was emaciated and had a body condition score of 1/9. The pig's death was attributed to prolonged starvation.

Date of Alleged Violation: July 26, 2022

9 C.F.R. § 2.31(e)(3) 9 C.F.R. § 2.31(e)(3) Institutional Animal Care and Use Committee (IACUC)

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals.

VATECH failed to ensure that proposals to conduct activities involving animals contained a complete description of the proposed use of the animals.

APHIS officials reviewed a protocol involving research with Syrian hamsters that failed to include the parenteral administration of Dimethyl sulfoxide (DMSO) to the hamsters. Several hamsters on the study developed minor skin lesions on their abdomen in the same area where the DMSO was administered. After contacting the veterinarian, no treatment was needed.

At the time of the inspection, the institution had already taken steps to notify the primary investigator that the approved protocol failed to

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include the use of DMSO. The principal investigator subsequently submitted a protocol amendment to the IACUC for review.

Date of Alleged Violation: September 30, 2022

9 C.F.R. § 2.38(f)(1) Handling.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

VATECH failed to handle animals as expeditiously and carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort.

A staff member receiving training on how to draw blood from gerbils as part of protocol 22-160, accidentally injured a gerbil during a blood draw procedure by restraining it too tightly. The staff member trainee placed the gerbil in a restraint device for a blood draw in accordance with the protocol. However, the staff member trainee used additional manual restraint, not understanding that the restraint device alone was adequate. After the staff member trainee noticed that the gerbil had become nonresponsive, the clinical veterinarian assessed the gerbil, found it to be moribund (non-responsive) and promptly euthanized the animal. This facility corrected this issue prior to the inspection.

Date of Alleged Violation: January 9, 2023

9 C.F.R. § 2.31(e)(3) Institutional Animal Care and Use Committee (IACUC) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals.

VATECH failed to ensure that proposals to conduct activities involving animals contained a complete description of the proposed use of the animals.

APHIS officials reviewed Protocol 20-187 that included exposing piglets to hypoxic conditions. The protocol stated that weight gain would be monitored, described the method for measuring body weight, and created a monitoring sheet and timeline for measuring body weights throughout the study. Additionally, the protocol identified twenty percent weight loss as a humane endpoint.

APHIS officials observed that the health records and monitoring sheets for the piglets involved had no body weights or other descriptions of weight gain recorded from October 26, 2022, to November 4, 2022. On November 4, 2022, the IACUC approved an amendment to add daily body condition scoring of piglets "to monitor"

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weight gain" (Amendment #10). Amendment #10 stated that "humane endpoints will remain the same as previously approved".

The records for November 5, 2022, and November 6, 2022, showed body condition scores recorded for the hypoxic pigs, but no body condition scores for the control group. No body condition scores were recorded for any pigs on November 7, 2022, and November 8, 2022.

The piglets finished the study on November 8, 2022. At no point during the study were body weights measured as stated in the protocol. Additionally, the protocol stated that blood samples would be collected from the pigs on specified days, but there was no record of blood sampling. The PI confirmed that no blood samples and body weights were collected.

On October 26, 2022, the facility changed the housing specified for the pigs in protocol 20-187 without IACUC approval. Amendment #10, approved by the IACUC on November 4, 2022, included a description of the new housing.

APHIS officials reviewed Protocol 21-023 that involved administering an infectious agent to calves. The facility reported an adverse event to the IACUC regarding the death of a calf used in the protocol. An internal review of the incident found that facility personnel failed to place an IV catheter in a calf within two days of administering the infectious agent as required by the protocol.

The calf received an inoculation on April 26, 2022, but failed to have an IV catheter placed by April 28, 2022, as required by the protocol. The calf became ill on May 2, 2022, at which time personnel sedated the calf, placed an IV catheter, and began IV fluid administration. The calf died despite these interventions.

Date of Alleged Violation: July 5, 2023

9 C.F.R. § 2.32(b) Personnel qualifications.

Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and § 2.31.

VATECH failed to make training and instruction available and review personnel qualifications with sufficient frequency to fulfill the research facility's regulatory responsibilities.

Animal husbandry staff responsible for daily observations of twentyeight gerbils that arrived at the facility on March 28, 2023, had inadequate training regarding monitoring the health of the gerbils. On

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April 4, 2023, research staff found one female and one male gerbil dead in their cages. The facility immediately euthanized one male gerbil that was severely ill. Two female gerbils required immediate supportive care and recovered.

An investigation concluded that prior to this adverse event, husbandry staff were inadequately trained to recognize abnormal behaviors and health in gerbils. Additionally, not all husbandry staff that provided care during this time had received hands-on training for this species.

On April 5, 2023, all husbandry staff received extensive training that addressed daily monitoring and clinical signs of disease to look for in gerbils.

The civil penalty amount is \$18,950 to resolve the alleged violation(s) above.

By paying the civil penalty, you are entering into this Settlement Agreement and:

- 1. Neither admitting nor denying the alleged violation(s) described above,
- 2. Agreeing to waive your right to a hearing, and
- 3. Agreeing to waive any action against USDA under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 et seq.) for fees and other expenses incurred in connection with this/these alleged violation(s) or any action against any USDA employee in their individual capacity.

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