



Wake Forest University
Medical Center Boulevard
Winston Salem, NC 27157

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: January 6, 2021

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 daily observation of all animals to assess their health and well-being; Provided however, that daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, 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 maintain mechanisms of direct and frequent communication with the attending veterinarian.

As documented in the July 28, 2021 inspection report, a macaque was recorded as being hypothermic throughout a four-hour anesthesia period and vomited during recovery. The research team failed to maintain complete recovery records and did not contact the attending veterinarian team to report timely and accurate information about the macaque's condition. The following morning, the attending veterinarian team found the macaque unresponsive in its enclosure, the animal's condition continued to deteriorate, and it was euthanized.

Date of Alleged Violation: March 17, 2021

9 C.F.R. § 2.38(f)(1) Miscellaneous. Handling. Handling of 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.

You failed to handle animals as expeditiously and carefully as possible to avoid trauma.

One rabbit that had undergone surgical procedures was handled for the administration of subcutaneous fluids. The staff member



administering fluids noted that the animal was dead at the completion of the fluid administration. Necropsy results indicated that the cause of death was mechanical asphyxiation.

Date of Alleged Violation: Between August 2020 and June 2021

9 C.F.R. § 2.32(c)(1)(iii) Personnel qualifications. Training and instruction of personnel must include guidance in at least the following areas: Humane methods of animal maintenance and experimentation including, Proper pre-procedural and post-procedural care of animals.

You failed to properly train personnel on humane methods of animal maintenance and experimentation.

As documented in the July 28, 2021 inspection report, a review of records of post-procedural care of four cats documented that researchers failed to comply with three post-procedural monitoring and care requirements as described in the IACUC-approved protocol, including, headwell cleaning frequency, appropriate body temperature care prior to return to housing enclosure after anesthesia and procedures and post-procedural pain relief administration.

Date of Alleged Violation: July 28, 2021

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 daily observation of all animals to assess their health and well-being; Provided however, that daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, 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 properly communicate with the attending veterinarian team.

As documented on the July 28, 2021 inspection report, multiple instances of failing to communicate to the attending veterinarian team in a timely and accurate manner were documented, including the following:

-Between July 2020 and July 2021, five incidences of cats not recovering as anticipated from neuroscience research procedures. In each instance the researcher indicated that the cats were quiet, alert and responsive. The researcher did not recognize any abnormal findings, but during same-day evaluations, the attending veterinarian team identified that the animals were experiencing pain, hypothermic, hyperthermic, in shock or in distress requiring immediate medical intervention by the attending veterinarian team.

-In May 2021, five rabbits had undergone IACUC-approved surgical procedures, but did not receive protocol-directed gabapentin. The research personnel responsible for administering the medication ran out of sufficient supply but did not contact the attending veterinarian team. The next day, the research team notified the attending veterinarian team noting a lack of medication administration.



Date of Alleged Violation: Between October 2022 and May 2023

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 daily observation of all animals to assess their health and well-being; Provided however, that daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, 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 report daily observations regarding animal health and welfare concerns.

As documented on the December 19, 2023 inspection report, the following incidents were not reported to the veterinarian team:

- In October/November 2022, an investigator failed to report an exposed subcutaneous vascular access port for four days when observed in a nonhuman primate. Another veterinarian reported the exposed port to the attending veterinarian team.

-In April 2023, an investigator administered an off-protocol drug to a macaque that resulted in the animal becoming excessively hypothermic with marked sedation. There was not a timely notification made to the attending veterinarian team.

- In May 2023, a macaque sustained laceration injuries when it was improperly placed in the same enclosure with another nonhuman primate. The injuries were discovered the next morning, but the incident was not reported to the attending veterinarian staff. The animal required anesthesia to repair a 4cm deep laceration with muscle involvement on the left chest and 1cm superficial laceration on the head.

Date of Alleged Violation: On or about January 2024

9 C.F.R. § 2.31(c)(7) Institutional Animal Care and Use Committee (IACUC) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall, review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

You performed activities not covered by the IACUC approved protocols.

As documented on the April 22, 2024 inspection report, an IACUC investigation documented that in January 2024 five vervets received anesthesia and MRI procedures not approved on their protocol.



Date of Alleged Violation: On or about January 2024

9 C.F.R. § 3.80(a)(2)(ii) Primary enclosures. Primary enclosures must be constructed and maintained to protect the nonhuman primates from injury.

You failed to construct and maintain enclosures to protect the nonhuman primates from injury.

As documented on the April 22, 2024 inspection report, a juvenile vervet suspended by her collar on a section of damaged chain link that supported a barrel device in the enclosure. The animal died due to the entrapment of the collar on the damaged chain.

The civil penalty amount is \$12,850 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.