



United States Department of Agriculture

Animal and Plant Health
Inspection Service

Emergency and
Regulatory Compliance
Services

Investigative and
Enforcement Services

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1st

March 11, 2025

Eastern Virginia Medical School
358 Mowbray Arch, PO Box 1980
Norfolk, VA 23501

**OFFICIAL WARNING
NOTICE OF ALLEGED VIOLATION**

Re: Reference number VA230019-AC

To Whom It May Concern:

We believe that you failed to comply with the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), and its implementing regulations, as described in the attached Official Warning. Our agency, the Animal and Plant Health Inspection Service (APHIS), is responsible for enforcing the AWA, and regulations and other agriculture laws that help prevent the spread of animal and plant pests and diseases and ensure the welfare of animals.

Although we have authority to pursue sanctions for the type of alleged violation(s) described in this Official Warning, we have decided not to pursue sanctions in this instance so long as you comply with the AWA and regulations. In the future, after providing you with an opportunity for a hearing, we may pursue administrative enforcement for each alleged violation described in this Official Warning.

What happens if I do not comply in the future? If you fail to comply in the future, we may pursue sanctions, that may include criminal penalties, for the alleged violations described in this Official Warning, in addition to any sanctions we may pursue for any future violations.

What should I do if I have questions? If you have any questions concerning this Official Warning, contact Thomas Jones at (510) 301-4111 or call our main office at (301) 851-2948.

I am a small business owner and have comments or concerns regarding APHIS's enforcement of animal and plant health laws. Who should I contact? If you have comments about APHIS's enforcement of animal and plant health laws, please contact the Deputy Administrator for Emergency and Regulatory Compliance Services, Hallie Zimmers, who is the APHIS Small Business Ombudsperson, at (301) 436-3157. If you prefer to comment to someone outside APHIS, contact the Small Business Regulatory Enforcement Ombudsman at <http://sba.gov/ombudsman>, email ombudsman@sba.gov, or 1-888-REG-FAIR. The SBA Ombudsman's office receives comments and annually evaluates federal agency enforcement activities for their responsiveness to the special needs of small businesses.

Sincerely,

Andrea McNally, Director
Investigative and Enforcement Services



UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE USDA OFFICIAL WARNING NOTICE OF ALLEGED VIOLATION	CASE NUMBER: VA230019-AC
	ALLEGED VIOLATOR: Eastern Virginia Medical School
	ADDRESS (City, State, ZIP Code): Norfolk, VA 23501

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: On or about January 12, 2023

9 C.F.R. § 2.31(c)(7) Institutional Animal Care and Use Committee (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.

EVMS failed to review and approve modifications for two protocols (19-015 and 20-018) which were enacted without IACUC review and approval.

In the first protocol (19-015), four female Chinchillas were kept on the study despite reaching and passing humane endpoints and the animals were also kept on the study far exceeding the 22-week timeline described in the protocol.

Protocol 19-015 states, "Any animal that experiences more than 20% weight loss will also be removed from the study." All of the animals were placed on the study upon arrival at the facility, and the program manager stated that none of the animals were transferred off the study.

1. Female Chinchilla (No. 2665L) was received by the facility on February 19, 2020 and weighed 404 grams upon intake. On July 29, 2020, the animal weighed 317 grams, a loss of 21.5% body weight. On August 6, 2020, the animal weighed 291 grams, a loss of 27.9% body weight, at which time the animal was euthanized.

2. Female Chinchilla (No. 2658R) was received by the facility on February 19, 2020 and weighed 468 grams upon intake. On April 30, 2020, the animal weighed 328 grams, a loss of 29.9% body weight. On May 5, 2020, the animal weighed 324 grams, a loss of 30.7% body weight. On May

11, 2020, the animal weighed 343 grams, a loss of 26.7% body weight. The animal was euthanized on May 13, 2020.

3. Female Chinchilla (No. 2668R) was received by the facility on February 19, 2020, and weighed 686 grams. On January 27, 2021, the animal weighed 534 grams a loss of 22.1% body weight. On August 23, 2021, the animal weighed 511 grams a loss of 25.5% body weight. The animal was euthanized on October 18, 2021.

4. Female Chinchilla (No. 2667L) weighed 668 grams upon intake. Study records show that on August 31, 2020, the animal weighed 500 grams, a loss of 25.1% body weight. Despite veterinary care, the animal died on September 9, 2020.

Protocol 19-015 also stated that animals will be weighed weekly. However, a review of the medical and study records showed that animals were not consistently weighed on a weekly basis.

In addition, protocol 19-015 stated that animals will be on study for 22 weeks, during which time they will undergo potentially painful procedures with anesthesia and analgesia provided. A review of records and discussion with the program manager showed that animals were kept on this protocol for periods of time longer than 22 weeks. Some animals remained on the protocol from March 2020 to November 2021 (21 months).

In protocol 20-018, changes were made to animal selection, procedures and care of rhesus macaques without IACUC reviewing and approving, required modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities

1. The age of animals (rhesus macaques) used on study was changed without IACUC approval. According to health records, two male animals ("HHA" and "AB67") were used on the study despite being older than the maximum age of 23 years described in the protocol.

2. The weight of animals used on study was changed without IACUC review or approval. The protocol states that animals will weigh between 8-22 kg. Five female animals (DN96, CX48, 6-191, 07U011, and EB74) were received on March 21, 2022 and placed on study. All five of the animals were all below the minimum weight required. The animals underwent physical exams shortly after intake and their body weights ranged from 4.9 kilograms to 7.3 kilograms.

3. The amount of sweetened beverage provided to the animals was increased without IACUC review and approval. An amendment approved June 7, 2021 added 500 mL of a sweetened beverage to the monkey's diet. Two monkeys ("HHA" and "35R") began this procedure on September 13,



2021, and records show that they consumed 1,000 mL of sweetened beverage on many days. The Program Manager stated that the monkeys were given refills of the sweetened beverage after consuming the first 500 mLs.

4. The duration of time that monkeys were given a sweetened beverage was lengthened without IACUC review or approval. Study records provided to USDA officials show that 2 animals (“HHA” and “35R”) were given this sweetened beverage from September 13, 2021 until April 25, 2022 (7-and-a-half -months), but the protocol stated that the sweetened beverage would only be provided for 3-6 months.

5. As part of recovering from an anesthetic event on study, animals were subjected to additional monitoring procedures which are not documented in the approved protocol. On September 22, 2022, 6 rhesus macaques underwent an insulin administration procedure and during recovery all of these animals were given dextrose injections and repeated blood draws. These procedures were not submitted to or reviewed by the IACUC nor were they documented as administrative changes.

Date of Alleged Violation: January 12, 2023

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 the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

EVMS failed to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of IV insulin, ultimately leading to the death of an animal and hours of unresolved, low blood glucose levels in others.

Medical records show multiple rhesus macaques experienced severe low blood sugar and prolonged anesthesia recovery times after a procedure where intravenous insulin was administered under anesthesia. After insulin administration, blood samples were taken at set intervals to monitor blood sugar for 30 minutes. Neither the protocol, nor an associated amendment, addressed low blood sugar as a potential side effect of insulin administration nor did they include any interventions to take should blood sugar fall to dangerously low levels.

On or about June 2022, a male rhesus macaque (DA9J) experienced an adverse event while on protocol (20-018) receiving intravenous insulin. According to his surgery/anesthesia monitoring record, he remained in “Stage 3” of anesthesia, which was defined by you as “animals who are unconscious or semi-conscious,” for over 4 hours until recordings cease. During this time, the animal received no medical care or monitoring of blood glucose, despite being hypoglycemic at the end of the 30-minute study. Based on medical records, the animal did not receive medical intervention until more than 7



hours after the end of the procedure, although he remained barely responsive and did not “fully recover” from the procedure. The animal did not improve and was euthanized on June 28, 2022 with the medical note that he did not “wake up” from the procedure and was “paralyzed, tonic/clonic”. The current Attending Veterinarian (AV) and program manager were unable to provide any additional information about the provision of care for this animal.

An additional 11 rhesus macaques underwent this same procedure and also received no monitoring of their blood glucose or medical interventions for low blood sugar despite having blood glucose levels that were so low they were undetectable by a handheld glucometer (less than 20 mg/dL) at the end of the procedure. All of these animals took an excessive amount of time to recover from their anesthesia, some over 5 hours. Per medical record review, prior documented recovery times for these same animals after other anesthetic events ranged from about 45 minutes to 1 hour.

In September 2022, the procedure was performed again on 6 of the same animals. Despite the addition of a minimal and ineffective intervention (sugar dextrose injections) and repeated blood sugar measurements, records show multiple animals had blood glucose levels that were undetectable by the handheld glucometer (less than 20 mg/dL) for prolonged lengths of time. Multiple animals suffered from incredibly low blood sugar levels without continuous medical intervention to resolve the issue.

Date of Alleged Violation: On or about May 2, 2023

9 C.F.R. § 2.31(c)(7) Institutional Animal Care and Use Committee (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.

Eastern Virginia Medical School (EVMS) failed to 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.

As documented on the May 2, 2023 inspection report, in protocol 21-003, IACUC approval is not being secured prior to enacting significant changes regarding the care and use of animals in ongoing activities. The protocol describes blood sampling for all animals on the pregnancy studies (adult female olive baboons) as being performed under ketamine sedation at 2–4-day intervals depending on the treatment group.

1. In 2023, the daily treatment records for a 17-year-old (No. 07105 “Alissa”) showed that the animal underwent blood draws at daily intervals



during multiple time periods:

January 27, 2023 through January 30, 2023
February 6, 2023 through February 11, 2023
March 3, 2023 through March 6, 2023

2. In 2021, the daily treatment records for 16-year-old, (No. 26876, "Jemma") showed that the animal underwent blood draws at daily intervals during multiple time periods:

May 12, 2021 through May 15, 2021
May 17, 2021 through May 20, 2021
May 23, 2021 through May 30, 2021
June 10, 2021 through June 13, 2021

The protocol (21-003) indicated that no more than 10ml/kg of blood be collected from each animal over a month period, however the daily treatment records do not specify the volume of blood being drawn each day. Thus, there is no way to track and verify that the total volume does not exceed the upper limit approved by the IACUC.

The protocol (21-003) states that all animals (adult female olive baboons) will be weighed monthly when they are on study. The protocol later states that animal weight is monitored weekly while the animal is on study when sedated. The records of 5 female baboons (ID Nos.: 26741, 26876, 27320, 07105, 03105) on the current protocol only have weights documented during their semi-annual physical and TB test, or during a surgical procedure. No further documentation of animal weights during this study period could be provided by the facility.

The protocol (21-003) describes an anticipated adverse event ("seizures") in approximately 10% of animals receiving a study drug from days 100-170 gestation. Due to this known adverse event, the protocol documents steps that will be taken for animals found non-responsive, actively seizing, or unconscious which includes removing the animal from the cage, performing a blood gas analysis and glucose level, catheter placement and potential supplementation of dextrose depending on the blood glucose result. A 16-year-old female Olive Baboon (No. 26876, "Jemma,") while receiving the study drug, was found unresponsive at 6:00 am by a technician on June 16, 2021. There are no records indicating treatment was provided as outlined in the protocol. The only entry is from the AV stating that the animal was found unresponsive at 6:00 am, but by the time the AV arrived the animal had consumed apple, was awake, quiet, alert, and responsive.



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.

APHIS OFFICIAL (Name):

Andrea McNally

OFFICE ADDRESS:

4700 River Road, Unit 85
Riverdale, MD 20737

APHIS OFFICIAL (Title):

Director, Investigative and Enforcement Services

DATE ISSUED:

3/11/2025

TELEPHONE

NUMBER:

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