



Inspection Report

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

Customer ID: **497**

Certificate: **52-R-0003**

Site: 001

EASTERN VIRGINIA MEDICAL
SCHOOL

Type: ROUTINE INSPECTION

Date: 12-JAN-2023

2.31(c)(7) Critical

Institutional Animal Care and Use Committee (IACUC).

Significant changes were enacted in two protocols without IACUC review and approval and/or appropriate handling and documentation of administrative changes.

In the first protocol (19-015), chinchillas were kept on study despite reaching and passing humane endpoints. Animals were also kept on study far beyond the 22-week timeline described in the protocol.

***Four female chinchillas were not removed from protocol 19-015 in accordance with the protocol's humane endpoint.

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 study upon arrival at the facility, and the program manager stated that none of the animals were transferred off the study.

1. Female chinchilla #2665L was received by the facility on 2/19/20 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 #2658R was received by the facility on 2/19/20 weighed 468 grams. On 4/30/20 the animal weighed 328 grams, a loss of 29.9% body weight. On 5/6/20 the animal weighed 324 grams, a loss of 30.7% body weight. On

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5/11/20 the animal weighed 343 grams, a loss of 26.7% body weight. The animal was euthanized on 5/13/20.

3. Female chinchilla #2668R was received by the facility on 2/19/20, and weighed 686 grams. On 1/27/21 the animal weighed 534 grams (22.1% weight loss). On 8/23/21 the animal weighed 511 grams (25.5% weight loss). The animal was euthanized on 10/18/21.

4. Female chinchilla #2667L weighed 668 grams upon intake. Study records show that on 8/31/20 the animal weighed 500 grams, a loss of 25.1% body weight. Despite veterinary care, the animal died on 9/7/20.

The procedure states that animals will be weighed weekly. However, review of medical and study records showed that animals were not consistently weighed on a weekly basis.

*** The protocol states that animals will be on study for 22 weeks, during which time they will undergo potentially painful procedures with anesthesia and analgesia provided. Review of records and discussion with the program manager show that animals were kept on this protocol for longer than 22 weeks, some animals remained on the protocol from March 2020 to November 2021 (21 months).

In the second protocol (20-018), changes were made to animal selection, procedures, and care of rhesus macaques without IACUC review and approval and/or appropriate handling and documentation of administrative changes.

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

***The weight of animals used on study was changed without IACUC approval. The protocol states that animals will weigh 8-22 kg. Five female animals (DN96, CX48, 6-191, 07U011, and EB74) received on March 21st, 2022 and placed on study were below the minimum weight required. The animals underwent physical exams shortly after intake and their

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body weights ranged from 4.9 kilograms to 7.3 kilograms.

***The amount of sweetened beverage provided to the animals was increased without IACUC 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.

***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 25th, 2022 (7.5 months), but the protocol stated that the sweetened beverage would only be provided for 3-6 months.

***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 22nd, 2022, 6 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.

For the above changes, these were not reviewed and approved by the IACUC or documented as administrative changes. Making significant changes to protocols without IACUC review and approval deprives the IACUC of the opportunity to provide oversight of animal activities and compliance with the Animal Welfare Act.

Correct by February 16, 2023 by ensuring that animal activities are accurately and completely described so that the

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IACUC can have oversight as required by the Animal Welfare Act regulations. At the time of the inspection, these protocols were closed and no longer active.

2.33(b)(2) Critical

Attending veterinarian and adequate veterinary care.

The facility 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.

In June 2022, a male rhesus macaque, "DA9J," experienced an adverse event while on protocol receiving intravenous insulin. According to his surgery/anesthesia monitoring record, he remained in "Stage 3" of anesthesia, defined by the facility as "animals are unconscious or semi-conscious," for over 4 hours until recordings cease. During this time, he received no medical care or monitoring of blood glucose, despite being hypoglycemic at the end of the 30-minute study. Based on medical records, he 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. Ultimately, the animal did not improve and was euthanized on 6/28/22 with the medical note that he did not "wake up" from the procedure and was "paralyzed, tonic/clonic". The current AV and program manager were unable to provide any additional information about

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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 the handheld glucometer (less than 20 mg/dL) at the end of the procedure. These animals all 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 so low they were undetectable by the handheld glucometer (less than 20 mg/dL) for prolonged lengths of time. This led to multiple animals suffering from incredibly low blood sugar without continuous medical intervention to resolve the issue.

Animals exposed to anesthesia and insulin require special attention and care to prevent low blood sugar, low body temperature, injury, and death. Animals with very low blood sugar may experience serious consequences including brain damage, loss of consciousness, and seizures.

Correct by February 16, 2023 by ensuring that appropriate methods are used to prevent, control, diagnose, and treat medical issues in animals, including the availability of emergency, weekend, and holiday care. At the time of the inspection, this protocol was closed and no longer active.

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This inspection was conducted with the CompMed Program Manager and IACUC representatives from the Office of Research.

The exit interview was conducted with the CompMed Program Manager, Director of Research Compliance, IACUC Chair, Institutional Official and IACUC representatives from the Office of Research.

Additional Inspectors:

DIANA CARE, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
497	52-R-0003	001	EASTERN VIRGINIA MEDICAL SCHOOL	12-JAN-2023

Count	Scientific Name	Common Name
000006	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000016	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000009	<i>Macaca mulatta</i>	RHESUS MACAQUE
000007	<i>Papio anubis</i>	OLIVE BABOON
000000	<i>Chinchilla lanigera</i>	CHINCHILLA
000038	Total	