



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: 02-MAY-2023

2.31(c)(7)

Repeat

Institutional Animal Care and Use Committee (IACUC).

IACUC approval is not being secured prior to enacting significant changes in protocol #21-003 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.

- In 2023, the daily treatment records for 17-year-old #07105 "Alissa" show that she underwent blood draws at daily intervals during multiple time periods. This includes, but is not limited to, daily blood draws during the following time periods: Jan 27th through January 30th, February 6th through Feb 11th, March 3rd through March 6th, 2023.

- In 2021, the daily treatment records for 16-year-old #26876 "Jemma" show that she underwent blood draws at daily intervals during multiple time periods. This includes, but is not limited to, daily blood draws during the following time periods: May 12th through 15th, May 17th through 20th, May 23rd through 30th, June 10th through 13th.

Increased blood draw frequency can have potential impacts on animal health and well-being and is a significant change to the current IACUC-approved protocol.

** The protocol states that all animals (adult female 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. Records of 5 female baboons (ID #: 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. Upon request, no further documentation of animal weights during this study period could be provided by the facility. Monitoring the animal's weight weekly is described in the protocol as a clinical parameter to be monitored to indicate adverse effects, pain, and/or distress to the animals. Failing to follow the protocol and significantly decreasing the frequency of weigh-ins without IACUC approval does not allow the IACUC to review a change in the study procedure, especially one that is directly related to monitoring animal health and welfare.

** The protocol 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

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depending on the blood glucose result. A 16-year-old female Olive Baboon #26876, "Jemma," while receiving the study drug, was found unresponsive at 6 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 attending veterinarian (AV) stating that she was found unresponsive at 6 am but by the time the AV arrived she had consumed some apples and was up and quiet, alert, and responsive.

Failing to follow the protocol and significantly changing the procedures performed on animals without IACUC approval does not allow the IACUC to review and either approve, require modifications in, or deny the proposed changes. Correct by ensuring that the IACUC reviews and approves, requires modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

This inspection and exit interview were conducted with facility representatives and the attending veterinarian.

Additional Inspectors:

Kristina D'Apice, VETERINARY MEDICAL OFFICER

GWENDALYN MAGINNIS, Nonhuman Primate Field Specialist

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
497	52-R-0003	001	EASTERN VIRGINIA MEDICAL SCHOOL	02-MAY-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
000008	<i>Macaca mulatta</i>	RHESUS MACAQUE
000006	<i>Papio anubis</i>	OLIVE BABOON
000036	Total	