

V A POLYTECHNIC INSTITUTE & STATE UNIVERSITY 300 TURNER STREET N.W., SUITE 4120 BLACKSBURG, VA 24061 Customer ID: **492** Certificate: **52-R-0012** Site: 001 VIRGINIA TECH

> Type: FOCUSED INSPECTION Date: 09-JAN-2023

2.31(e)(3) Critical Repeat Institutional Animal Care and Use Committee (IACUC).

Two IACUC-approved protocols do not accurately or completely describe the animal activities being performed.

***Protocol 20-187 ("IACUC 20-187 Protocol Application Rev3") Experiment 2 is an activity that includes exposing piglets to hypoxic conditions. The protocol says weight gain will be monitored. A description of a method of measuring body weight is included in the protocol. A monitoring sheet was developed for the protocol, which includes a column in which weights may be recorded in kilograms. A timeline was created showing that body weights would be measured ("weigh animal") throughout the study, depending on the length of time the animal would remain on the protocol. The protocol also identifies 20% weight loss as a humane endpoint. All of this documentation was submitted to the IACUC prior to the IACUC's approval of the protocol.

On October 26th, 2022, a group of piglets was placed on the protocol; the health records and monitoring sheets for this group were reviewed. Half of the piglets were assigned to a hypoxic group while the other half served as controls. From October 26th, 2022 to November 4th, 2022, there are no body weights or other descriptions of weight gain recorded. On November 4th, 2022, an amendment (Amendment #10) was approved by the IACUC to add a daily body condition scoring

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of piglets "to monitor weight gain". Amendment #10 also stated that "humane endpoints will remain the same as previously approved". On November 5th and 6th, 2022, body condition scores were noted in the records for the hypoxic pigs only. Body condition scores were not recorded for any pigs on November 7th and 8th, 2022. The piglets finished out the study on November 8th, 2022, and at no point 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, and there is no record of blood sampling being performed. The PI confirmed that blood samples and body weights were not collected.

The protocol also says pigs will be housed in a "wire pet cage (24"L x 18"W x 19"H) within a custom made hypoxia chamber ("30"L x 20"W x 20"H) with a clear plexiglass viewing pane." Instead, starting on October 26, 2022, the pigs were housed in a brand-new customized hypoxia chamber which is intended to improve animal welfare by allowing social housing. Amendment #10, approved by the IACUC on November 4th, 2022, included a description of the new housing.

***On Protocol 21-023, an adverse event occurred and was reported to the IACUC. The facility's internal review of the incident lead to the finding that that facility personnel had not placed an IV catheter in a calf within 2 days of administering the infectious agent as was required by the protocol. The animal was inoculated on April 26, 2022 and should have had an IV catheter placed by April 28th, 2022. The animal became ill on May 2nd, 2022 at which time the animal was sedated, an IV catheter was placed, IV fluid administration began, but despite these interventions the animal died shortly thereafter. The protocol states that "within 1-2 days of oocyst challenge, calves will have a jugular catheter placed". Furthermore, the protocol states, "the catheters are designed to facilitate administration of rescue therapy in the event that a calf becomes severely debilitated and requires supportive care."

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Incorrectly or incompletely describing animal activities undermines the IACUC's ability to review and approve these activities. IACUC oversight of animal activities is essential for ensuring animal welfare and oversight of research using animals.

Correct by ensuring that animal activities are accurately and completely described so that the IACUC can have oversight as required by the Animal Welfare Act regulations.

2.36(b)

Annual report.

The facility's annual report for FY 2022 did not accurately report all animals used in or held for research. The FY 2022 annual report reported no gerbils. Review of facility records showed that the facility used 24 gerbils beginning on September 27th, 2022 on protocol 22-160. Correct reporting of all required information on the annual report is required so that the public, USDA APHIS Animal Care, and Congress can have knowledge of the number, type, and pain category of animals used- or held for use in research. Correct by February 11th, 2023, by submitting a corrected FY 2022 annual report to USDA APHIS Animal Care.

2.38(f)(1) Critical

Miscellaneous.

On September 30th, 2022 a staff member accidentally injured a gerbil during a blood draw procedure by restraining it too tightly. A clinical veterinarian was training staff members on how to draw blood from gerbils as part of protocol 22-160. In accordance with the training section of the protocol, a gerbil was placed in a restraint device for a blood draw. However, the staff member trainee used additional manual restraint to restrain the animal, not understanding that the restraint device alone was adequate. The staff member trainee noticed that the gerbil had become nonresponsive in the restraint device and was then assessed by the clinical veterinarian, who found it to be moribund (non-responsive) and promptly

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euthanized the animal The handling was not done as carefully as possible leading to the gerbil being euthanized. All animal handling including immobilization for training must be done as expeditiously and carefully as possible in a manner that does not cause trauma, stress, physical harm, or unnecessary discomfort. This issue was corrected prior to the inspection.

3.13(a)(3)

Veterinary care for dogs.

The facility's written "Canine program of veterinary care" (SOP#504.01, effective date 2/23/22) does not include a schedule of vaccinations for dogs. In the written program, veterinary care of the dogs is delegated by the Attending Veterinarian to "trained and experienced veterinarians within the Animal Resources and Care Division (ARCD) of the Office of Research and Innovation (ORI) and to veterinarians employed by the Virginia-Maryland College of Veterinary Medicine (CVM)."

Section III subpart D(s) the of the SOP states, "The vaccination history of each dog is reviewed by the veterinarian as part of the receiving process. Animals not current on core vaccinations are provided those vaccinations. The veterinarian uses his/her professional judgment, the age of the animal, and the vaccination history to determine if a full series or a booster vaccination is necessary for any missing or overdue vaccine." Review of medical records for dogs used on CVM teaching protocols in the late summer and fall of 2022 show that many dogs were vaccinated upon intake for rabies, leptospirosis, and distemper/parvovirus. Some dogs received booster vaccinations. Some dogs were vaccinated despite having documentation of recent vaccination at their institution of origin.

The written program of veterinary care must include a schedule for vaccinations (including rabies, parvovirus, and distemper) approved by the Attending Veterinarian to ensure consistent guidance to all veterinarians and staff tasked with

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providing care for the dogs.

Correct by March 11, 2023 by having the Attending Veterinarian update the written program of veterinary care for dogs to include a schedule of vaccinations for contagious and/or deadly disease of dogs including rabies, parvovirus, and distemper.

This inspection was conducted with the IACUC Administrator, facility representatives, and staff veterinarians. The exit interview was conducted with the IACUC Administrator, IACUC Chair, IACUC representatives, facility representatives, Attending Veterinarian, Staff Veterinarians, Associate Vice President of Scholarly Integrity and Research Compliance, Vice President of Research, and other research personnel.

Additional Inspectors:

DIANA CARE, VETERINARY MEDICAL OFFICER

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United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 492 Inspection Date: 09-Jan-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
492	52-R-0012	001	VIRGINIA TECH	09-JAN-2023

Count	Scientific Name	Common Name
000019	Equus caballus	DOMESTIC HORSE
000000	Sus scrofa domestica	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000000	Bos taurus	CATTLE / COW / OX / WATUSI
000000	Meriones unguiculatus	MONGOLIAN GERBIL
000000	Canis familiaris	DOG ADULT

000019 **Total**