



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 25, 2019

Re: Animal Welfare Assurance
A3208-01 [OLAW Case 1D]

Dr. Theresa S. Mayer
Vice President for Research
Virginia Polytechnic Institute and
State University – Blacksburg
(b) (4) Burruss Hall, (Mail Code 0244)
Blacksburg, VA 24061-0244

Dear Dr. Mayer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 30, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Polytechnic Institute and State University, following up on an initial telephone report on December 20, 2018. According to the information provided, OLAW understands that a guinea pig died of anorexia following transportation stress. Laboratory Animal Resources (LAR) staff had not been properly trained and failed to follow the protocol, failed to adhere to humane endpoints, and failed to maintain adequate records.

The corrective actions consisted of the Principal Investigator, Office of the University Veterinarian, and LAR staff discussing protocol requirements and streamlining documentation. The Institutional Animal Care and Use Committee required the PI to use a mechanism outside of LAR to ensure that the protocol is followed. The IACUC also required all LAR staff to be retrained and evaluated for competency.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



Division of Scholarly Integrity and
Research Compliance
Institutional Animal Care and Use
Committee (IACUC)
North End Center
300 Turner St NW, Suite 4120
Blacksburg, Virginia 24061
P: (540) 231-0931 F: (540) 231-0959
Email: IACUCadmin@vt.edu
www.research.vt.edu/iacuc

January 30, 2019

Axel Wolff, DVM
Director, Divisions of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Final report regarding serious protocol noncompliance at Virginia Tech [Assurance #A-3208-01]

Dear Dr. Wolff:

Virginia Tech, in accordance with Assurance A-3208-01 and PHS Policy IV.F.3., provides this report of serious noncompliance regarding a guinea pig death on a protocol entitled "Conduction and Arrhythmias – Guinea Pig." This incident was first reported to Dr. Brent Morse, OLAW, on December 20, 2018 via a telephone call by (b) (6)

On November 1, 2018, the Office of the University Veterinarian (OUV) notified the IACUC office that a guinea pig was found dead due to complications of transportation stress-induced anorexia. Additionally, after investigation it was determined that personnel failed to adhere to IACUC-approved protocol procedures and humane endpoints, and failed to maintain appropriate animal-related records. The PI specified in the protocol that personnel from Laboratory Animal Resources (LAR), overseen by the Attending Veterinarian and trained by the OUV, would perform study procedures. It was determined that personnel had not been appropriately trained regarding protocol expectations and to perform protocol procedures. The IACUC discussed the incident at the December 17, 2018 convened meeting, approved corrective steps taken and requested additional corrective actions from the PI and OUV:

- The IACUC required a meeting between the PI, OUV, and LAR staff to clarify protocol expectations and streamline the animal records system. Documentation of this meeting and action plan must be submitted by January 15, 2019 for review.
- The IACUC required the PI create a review mechanism outside of LAR personnel to ensure appropriate protocol expectations are met. Documentation of this meeting and action plan must be submitted by January 15, 2019 for review.
- The IACUC required all LAR staff be re-trained by the OUV and documentation of training and competency be submitted by January 15, 2019 for review.
- All above items were received on January 11, 2019.

The funding source for this guinea pig is the National Heart, Lung, and Blood Institute (LOG-R01HL102298C, R01HL141855A, and R01HL138003A). Per PHS requirement the PI has been informed that he must work with his grant administrator to determine any funding related actions that must be taken.

Virginia Tech is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6)

(b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Theresa Mayer
Vice President for Research and Innovation
Institutional Official
Virginia Tech

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 20, 2019 10:01 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Final Reports

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for these reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Tuesday, February 19, 2019 12:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Final Reports

To Whom It May Concern,

Attached, please find three final noncompliance reports.

If you have any questions, please feel free to call (b) (6)

Thanks,
(b) (6)

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(b) (6)



Initial Report of Noncompliance

By: *[Signature]*

Date: 12/20/18

Time: 3:45

Name of Person reporting: (b) (6)
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: Virginia Tech.
 Assurance number: A3208

Did incident involve PHS funded activity? Yes
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened? One geriatric retired male breeder not properly monitored; lack of monitoring documentation; animal care staff not trained on end-points.

Species involved: G.P.
 Personnel involved:
 Dates and times: End of Oct 2018
 Animal deaths: Yes

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
 Case # _____