



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

October 10, 2018

Re: Animal Welfare Assurance
#A3227-01 (OLAW Case 5J)

Dr. John F. Manning, Jr.
Chief Operating Officer
Vanderbilt University Medical Center
D-3300 Medical Center North
11611 21st Avenue South
Nashville, Tennessee 37232-2104

Dear Dr. Manning,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 26, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, following up on an initial telephone report on August 29, 2018. According to the information provided, OLAW understands that two rats sustained tail lesions after being injected with intravenous dye, although this administration route was not approved on the protocol. The rats were also not being monitored as required.

The corrective actions consisted of retraining the laboratory staff, amending the protocol to include the procedure, and developing a monitoring process and documentation.

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 institution 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
Director of Animal Welfare



September 26, 2018

*John F. Manning, Jr., Ph.D., MBA
Chief Operating Officer
Corporate Chief of Staff*

Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Regarding: Vanderbilt University Medical Center - Assurance #A-3227-01

Dear Dr. Wolff:

In accordance with PHS Policy IV.F.3.a, Vanderbilt University Medical Center (VUMC)/ Vanderbilt University (VU) or the Department of Veterans Affairs Tennessee Valley Healthcare System (TVHS) Institutional Animal Care and Use Committee (IACUC) is self-reporting an incident involving two rats found with tail lesions. A preliminary report was filed via phone with OLAW on August 29, 2018.

This is the final report provided to the Office of Laboratory Animal Welfare (OLAW) regarding the issue.

Species Involved: Rat

Funding Source: Agency & Departmental

Incident Description:

During the July 2018 semi-annual IACUC inspections, the inspection team identified two rats that had tail lesions due to an IV injection of a fluorescent dye on the previous day. After review of the protocol, it was found that this administration route was not approved and that the laboratory was not monitoring the animals, as approved in the protocol.

IACUC Actions Taken and Corrective Plans:

This information was brought to the IACUC at a convened meeting on July 25, 2018. The IACUC discussed the facts and voted to require that the Principal Investigator (PI) review and retrain their staff on the procedures approved in the protocol. The IACUC indicated that the laboratory staff and PI must not perform the procedure until retraining was completed approved and that the laboratory should develop a process for monitoring the animals.

Implementation of Changes:

In correspondence dated August 14, 2018, the PI assured the IACUC that they have submitted an amendment to add the procedure; reviewed and retrained the staff on the approved protocols; created a record keeping book for monitoring animals; and

that all the laboratory staff will take training with the veterinary group on injection techniques.

At the August 22, 2018 convened IACUC meeting, the committee discussed the PI's response to the incident and found these actions addressed the concerns and provided an appropriate plan to prevent reoccurrence of the issue. The committee voted that the issue was reportable to OLAW.

As always, Vanderbilt University Medical Center, Vanderbilt University and the Department of Veterans Affairs Tennessee Valley Healthcare System remain committed to the highest standards of compliance related to the humane use of animals in research, teaching and testing.

Please do not hesitate to contact me or Dr. Scott Bury at (b) (6) with any questions.

Sincerely,

(b) (6)

John P. Manning, Jr., PhD, MBA
Institutional Official

cc:

(b) (6)

Scott D. Bury, PhD, CPIA, Director, OAWA
Ronald B. Emeson, PhD, IACUC Chair
James R. Swearingen, DVM, DACLAM, Global Director, AAALAC International
Jeanne M. Wallace, DVM, DACLAM, Attending Veterinarian

(b) (6)

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(b) (6)



Initial Report of Noncompliance

By: *aw*

Date: *8/29/18*

Time: *1:20*

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: *Vanderbilt U*

Assurance number: *A3227*

Did incident involve PHS funded activity? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

2 rats had tail lesions from injection; procedure met an protocol

Species involved: *Rats*

Personnel involved:

Dates and times:

Animal deaths:

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

Treat rats, Amend protocol, Retraining by vet

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____