



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 27, 2019

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

Dr. John F. Manning, Jr.
Chief Operating Officer
Vanderbilt University Medical Center
(b) (4) 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 February 27, 2019 letter providing a final report regarding a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the Department of Veterans Affairs Tennessee Valley Healthcare System (TVHS), a covered component of Vanderbilt University Medical Center, and following up on an initial report on January 29, 2019. According to the information provided, OLAW understands that two mice died due to lack of water caused by a missing water bottle.

The corrective actions consisted of retraining the TVHS animal care staff on policies, standard operating procedures, daily health checks, and prompt reporting of animal health concerns to the veterinarians. The staff responsible was counseled and disciplined. The Vanderbilt Institutional Animal Care and Use Committee (IACUC) will continue monitoring the TVHS animal care and use program.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a recurrence of this problem. OLAW concurs with the actions taken by the IACUC and TVHS to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director of Animal Welfare
Michael Fallon, D.V.M., Ph.D., VA Chief Veterinarian
James Trout, Ph.D., ORO



February 27, 2019

*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 mice found dead without access to water in the cage. A preliminary report was filed via phone by VUMC with OLAW on January 29, 2019.

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

Species Involved: Mouse

Funding Source: Veterans Affairs

Incident Description:

The report from TVHS indicated that on January 2nd, one mouse was found dead in a cage with no water bottle. The TVHS Animal Care Technician (ACT) supplied water and wet food to the remaining mice at that time. The following day an additional mouse was found dead.

IACUC Actions Taken and Corrective Plans:

The information gathered by OAWA during its investigation, which included a response by TVHS outlining steps already taken to address the incident, was brought to the attention of the IACUC at a convened meeting on January 23, 2019. The TVHS corrective action consisted of a review of all relevant policies and SOPs with TVHS ACTs, clarification of duties for the staff regarding room checks and reporting of animal health concerns to the Division of Animal Care Veterinary staff, and counseling and disciplinary actions for relevant staff.

The IACUC discussed TVHS' response to the incident and found it addressed the concerns and provided an appropriate plan to prevent reoccurrence of the issue. The IACUC considers the event closed but will continue to monitor

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john.manning@vanderbilt.edu

and assist the TVHS in assuring that all animal care requirements are being met.

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 F. Manning, Jr., PhD, MBA
Institutional Official

cc:

(b) (6)

Gary L. Borkowski, DVM, MS, DACLAM, Global Director, AAALAC
Scott D. Bury, PhD, CPIA, Director, OAWA
Ronald B. Emeson, PhD, IACUC Chair
Sheron L. Salyer, DNSc, RNC, CHRC, VHA-CM, VA Research Compliance Officer
Jennifer Vedral-Baron, MN, ARNP, NP-C, FAANP, FACHE,
Dept. of Veterans Affairs Health System Director
Jeanne M. Wallace, DVM, DACLAM, Attending Veterinarian
Mike Walsh, MS, VA Administrative Officer

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 27, 2019 2:30 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letters from VUMC A3227-01

Thank you for providing these reports. I will forward them to Dr. Wolff who will send official responses.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Wednesday, February 27, 2019 12:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Letters from VUMC A-32227-01

Good Morning,
Please find attached three letters from the Vanderbilt IACUC. One of the three is a followup letter with more information on the #5R incident. Let me know if you have any questions.

Regards,
(b) (6)

(b) (6)



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FOR EXPRESS MAIL:

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Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 1, 2019

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

Dr. John F. Manning, Jr.
Chief Operating Officer
Vanderbilt University Medical Center
(b) (4) 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 January 29, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the Department of Veterans Affairs Tennessee Valley Healthcare System which is a covered component of the Vanderbilt University Medical Center, following up on an initial telephone report on the same day. According to the information provided, OLAW understands that two mice died due to lack of water caused by a missing water bottle.

The immediate action taken upon discovery consisted of providing water and wet food to the surviving mice. The corrective actions consisted of retraining the animal care staff on policies and procedures, on the conduct of daily health checks, and on reporting of health concerns to the veterinary staff. The individuals responsible were counseled and disciplined. The Vanderbilt Institutional Animal Care and Use Committee (IACUC) is continuing to investigate.

Thank you for informing OLAW about this matter. We will keep this case open and await the final report after the IACUC has completed its investigation.

Sincerely,

(b)(6)

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

cc: IACUC Chair
Director of Animal Welfare
Michael Fallon, D.V.M., Ph.D., VA Chief Veterinarian
James Trout, Ph.D., ORO



January 29, 2019

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, 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 responding to the OLAW letter dated December 19, 2018, regarding OLAW Case #5L. OLAW requested an update on February 1, 2019, regarding new hires and the status of success or failure in providing adequate food and water to research animals (mice).

A3227-5L
The Division of Animal Care (DAC) provided information, related to the OLAW request, to the IACUC at the December 2018 and January 2019 IACUC meetings as required by the IACUC.

The DAC reported at the January 23, 2019 convened IACUC meeting that the mouse census is approximately 24,500 cages; therefore, 24 Animal Care Technicians (ACTs) are needed to appropriately maintain this number of cages. The DAC is currently staffed with 22 ACTs.

As of the January 23rd IACUC meeting, no new cases have been reported at VUMC/VU. The IACUC will continue to require reporting of new hires and the status of success or failure in providing adequate food and water to research animals until the Committee is satisfied that staffing and animal welfare concerns have been resolved.

A3227-5R
One case where mice were found dead without access to water at TVHS was self-reported to the IACUC on January 17, 2019. The report indicated that on January 2nd, one mouse was found dead in a cage with no water bottle. Records indicated the animals were without water access for approximately 24 hours. The TVHS supplied water and wet food to the remaining mice at that time. The following day an additional mouse was found dead. The TVHS corrective action consisted of a review of all relevant policies and SOPs with TVHS animal care staff, clarification of duties for staff regarding room checks

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and reporting of animal health concerns to the DAC Veterinary staff, and counseling and disciplinary actions for relevant staff. The IACUC has reviewed the response and will continue to monitor the situation and assist the TVHS in assuring that all animal care requirements are being met. A separate report of the incident will be filed with OLAW upon completion of the IACUC investigation.

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 E. Manning, Jr., PhD, MBA
Institutional Official

cc:

(b) (6)

Gary L. Borkowski, DVM, MS, DACLAM, Global Director, AAALAC
Scott D. Bury, PhD, CPIA, Director, OAWA
Ronald B. Emeson, PhD, IACUC Chair
Sheron L. Salyer, DNSc, RNC, CHRC, VHA-CM, VA Research Compliance Officer
Jeanne M. Wallace, DVM, DACLAM, Attending Veterinarian
Mike Walsh, MS, VA Administrative Officer
Jennifer Vedral-Baron, MN, ARNP, NP-C, FAANP, FACHE,
Dept. of Veterans Affairs Health System Director

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 30, 2019 10:38 AM
To: (b) (6); R: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Bury, Scott Douglas
Subject: RE: Letter from VUMC A-3227-01

Thank you for providing this update (b) (6). Doctor Wolff will reply soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Wednesday, January 30, 2019 9:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6); Bury, Scott Douglas <scott.d.bury@vumc.org>
Subject: Letter from VUMC A-3227-01

Good morning,
Attached is the requested response from VUMC regarding case #5L.
Please let me know if you have any questions.

Thanks,
(b) (6)

(b)(6)





Initial Report of Noncompliance

By: *aw*

Date: *1/29/18*

Time: *12:15*

Name of Person reporting: *Scott Barry*

Telephone #: *(b)(6)*

Fax #:

Email:

Name of Institution: *Vanderbilt U / VA performance site*

Assurance number: *A3227*

Did incident involve PHS funded activity? ☐

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *Aging study*

Cages without water bottles + food mouse. Another mouse died next day.

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths: *2*

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

Retrain, revise SOPs

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____