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) 480-3387

November 12, 2021

Re: Animal Welfare Assurance
#A3227-01 (OLAW Case 6M)

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 November 5, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Vanderbilt University Medical Center, following up on an initial telephone report on August 4, 2021. According to the information provided, OLAW understands that four mice died due to lack of food. During weaning of the mice, the laboratory staff had used a new cage which did not have food. The problem was not identified during the daily health check which may have been complicated due to the room being on a reverse light cycle.

The corrective actions consisted of the Principal Investigator counseling the laboratory staff, retraining the staff on checking cages for food/water, and directing the staff to use the correct cages prepared with food. Signs were modified to identify the cages that are prepared in advance for use by investigators and the husbandry staff was retrained.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution 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

VANDERBILT UNIVERSITY MEDICAL CENTER

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

November 5, 2021

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 one cage of mice found dead without access to food, in a reverse light cycle room. A preliminary report was filed via phone with the Office of Laboratory Animal Welfare (OLAW) on August 4, 2021.

This is the final report provided to the OLAW regarding the issue.

Species Involved: mice
Funding Source: NIDA: 1 F31 DA051153-01A1, NIH: 1K99DA042111-01 Departmental, and other agencies.

Incident Description: On June 14, 2021, the Office of Animal Welfare Assurance (OAWA) received a report from the Division of Animal Care (DAC) regarding an incident in which one cage of mice was found without access to food. Two of the four mice in the cage were found dead and two were found lethargic. Despite treatment, the lethargic mice subsequently died.

The IACUC investigation showed that when weaning the mice, laboratory personnel selected clean cages from a DAC cart staged for cage changing, rather than the clean-cage station designated for laboratory personnel which holds cages pre-filled with food. Additionally, this room is in reverse light cycle, which made identifying cages without food more challenging.

IACUC Actions Taken and Corrective Plans:
The information gathered by OAWA during its investigation was brought to the attention of the IACUC at a convened meeting on July 28, 2021.

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D-3300 Medical Center North
Nashville, TN 37232-2104

tel 615.322.0230
fax 615.343.7286
john.manning@vanderbilt.edu

The IACUC discussed the facts and voted to require that the Principal Investigator (PI) retrain their laboratory personnel and provide a plan to the IACUC that addressed how the laboratory would prevent a recurrence of this type of non-compliance. The IACUC also voted to require that the DAC modify signage in the areas where cage changing supplies are stored for investigators and confirm that staff assigned to the room were adequately trained to perform daily checks for food, water, and mouse health.

Implementation of Changes: In correspondence dated September 1, the PI assured the IACUC that they discussed this incident with their laboratory personnel. In addition, the PI indicated that a monitoring plan was established and that personnel were trained to the plan which includes checking cages for the presence of food and water. Finally, personnel were reminded to use the supplies specifically made available in the room for researchers.

In correspondence dated September 14, 2021, the DAC assured the IACUC that signage had been modified, additional signage had been posted, and DAC staff had been retrained.

At its convened meeting on September 22, 2021, the IACUC discussed PI's and DAC's responses to the incident, and found the actions addressed the concerns and provided appropriate plans to prevent recurrence of the issues. The IACUC considers the incident closed.

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 [redacted] (b) (6) with any questions.

Sincerely,

[redacted] (b) (6)

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

cc: [redacted] (b) (6)
Ronald B. Emeson, PhD, IACUC Chair
Jeanne M. Wallace, DVM, DACLAM, Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 12, 2021 8:02 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: VUMC Final Letters to OLAW

Thanks for these reports, (b) (6) I'll send replies soon.
Axel Wolff

From: (b) (6)
Sent: Monday, November 8, 2021 11:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: VUMC Final Letters to OLAW

Good Evening,
Attached are the Vanderbilt University Medical Center's (A3227-01) final letters to OLAW regarding several incidents of non-compliance.
Please let me know if you have any questions.
Thank you,
(b) (6)

(b) (6)

A3227-6M

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: (b) (6)

Date: 8/4/21 Time: 3:00

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? Yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

Mouse pups left in food hopper by PI. Could not get to water + died.

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths:

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

Counsel

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____