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

December 22, 2021

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

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 December 20, 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 October 1, 2021. According to the information provided, OLAW understands that two mice in one cage died and one required euthanasia due to lack of food. A "Do Not Feed/Water" sign was on the cage which meant laboratory staff would be feeding the animals, but this did not occur. The problem was not identified during the daily health check.

The corrective actions consisted of counseling the Principal Investigator who indicated that the individual responsible had performance issues and left the institution. The PI has no active animal studies but will train staff carefully on animal policies/procedures should studies resume. The animal care staff was counseled and retrained on how to handle "Do Not Feed/Water" cages and on conducting daily health checks.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a 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 and notes that ongoing vigilance must be exercised to ensure that both researchers and husbandry staff are attentive in providing food/water to all animals. Thank you for keeping OLAW apprised on this matter.

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

December 20, 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. A preliminary report was filed via phone with Office of Laboratory Animal Welfare (OLAW) on October 1, 2021.

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

Species Involved: Mice
Funding Source: Departmental

Incident Description: On August 31, 2021, the Office of Animal Welfare Assurance (OAWA) received a report that one cage with three mice was found without food. Two of the three animals were found dead, the third animal was lethargic and despite treatment, was subsequently euthanized.

The IACUC investigation found that a Do Not Feed/Do Not Water card had been placed on this cage indicating that the laboratory was responsible for feeding. The laboratory staff indicated they thought the cage had been euthanized weeks earlier. Additionally, the person responsible for the cage had lost their ID badge and could no longer enter the animal facility and has since left the institution.

1161 21st Avenue South
D-3300 Medical Center North
Nashville, TN 37232-2104

tel 615.322.0230
fax 615.343.7286
john.manning@vanderbilt.edu

The Division of Animal Care (DAC) Animal Care Technicians (ACT) did not note any animal health concerns with this cage during the daily checks.

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 September 22, 2021. The IACUC discussed the facts and voted to require that the 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 review and update, as necessary, procedures for monitoring animals (including procedures for monitoring animals under "Do Not Feed/Do Not Water" restrictions and for performing secondary checks) to determine why the lack of food was not discovered prior to animal death, and to discuss or retrain all relevant DAC staff on any updates as needed.

Implementation of Changes: In correspondence dated October 26, 2021, the PI informed the IACUC there were emerging performance issues with the person responsible for the cage that coincided with the noncompliance incident. Currently the PI has no active animal studies and assured the IACUC that if they begin animal research again, they will train all new personnel emphasizing the importance of following relevant IACUC policies and procedures.

In correspondence dated October 12, 2021, the DAC Operations management team reviewed the relevant standard operating procedures (SOPs) and deemed that no revisions of these documents were needed. The Facility Manager met with relevant DAC staff to discuss the incident, identified opportunities for improvement, and retrained them on SOPs.

At its convened meeting on October 27, 2021, the IACUC discussed the 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 [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: Wednesday, December 22, 2021 8:22 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: VUMC Final Letter to OLAW

Thank you for this report, (b) (6) I will send a response soon.
Happy Holidays to you as well.
Axel Wolff

From: (b) (6)
Sent: Tuesday, December 21, 2021 3:45 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] VUMC Final Letter to OLAW

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good Afternoon,
Attached is the Vanderbilt University Medical Center's (A3227-01) final letter to OLAW regarding an incident of non-compliance.
Please let me know if you have any questions.
Thank you and Happy Holidays!
(b) (6)

(b) (6)

A3227—6N

Office of Laboratory Animal Welfare
OLAW

Initial Report of Noncompliance

By: [redacted] (b) (6)

Date: 10/1/21

Time: 9:30

Name of Person reporting: [redacted] (b) (6)
Telephone #: [redacted] (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?
Mice on special diet. Investigator thought animals were euthanized so didn't feed. 2 mice died, 1 moribund + euth. Used signs that say investigator will feed so caretakers only top off if feeder is very low.

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths: 3

Projected plan and schedule for correction/prevention (if known): ________________
Investigator left institution.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # __________