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

October 1, 2021

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

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 September 28, 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 seven mouse pups died due to not being able to access water. A laboratory staffer had weaned the cage, placed the pups on top of the food in the wire bar lid, and put the cage back on the rack. The location of the pups prevented visualization during the daily health check.

The corrective action consisted of directing the Principal Investigator to counsel and retrain the laboratory staff. This was completed and a new workflow plan was implemented in the laboratory to improve the animal handling.

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*

September 28, 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 mice. A preliminary report was filed via phone with OLAW on August 4, 2021.

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

**Species Involved**: mouse
**Funding Source:** NIH #CA116087
**Incident Description:**
On July 9, 2021, the Office of Animal Welfare Assurance (OAWA) received a report that seven mouse pups were found dead without access to water. While weaning the litter, a laboratory associate placed the mouse pups on top of the food in the wire bar lid and returned the cage to the rack. Unfortunately, the type of caging prevented viewing of the pups in the food hopper during routine health checks.

**IACUC Actions Taken and Corrective Plans:**
The information gathered by OAWA during its investigation was brought to the IACUC at a convened meeting on July 28, 2021. The IACUC discussed the facts and voted to require that the Principal Investigator (PI) provide a plan to the IACUC that addressed how the laboratory would prevent a recurrence of this type of non-compliance. The PI was also asked to discuss the non-compliance with the laboratory and provide retraining to all relevant personnel.

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Nashville, TN 37232-2104

tel 615.322.0230
fax 615.343.7286
john.manning@vumc.org

**Implementation of Changes:** In correspondence dated August 23, 2021, the PI assured the IACUC that they had discussed the non-compliance with the laboratory, implemented a new plan for workflow improvements to prevent a recurrence, and retrained all relevant personnel.

At its convened meeting on August 25, 2021, the IACUC discussed the PI's response to the incident and found the actions taken addressed the IACUC's concerns. 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 (b) (6) with any questions.

Sincerely,

(b) (6)

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

cc: (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, September 29, 2021 7:55 AM
**To:** (b) (6)
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)
**Subject:** RE: VUMC Final Letter to OLAW

Thanks for the report, (b) (6) We'll send a response soon.
Axel Wolff

**From:** (b) (6)
**Sent:** Tuesday, September 28, 2021 5:15 PM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
**Cc:** (b) (6)
**Subject:** VUMC Final Letter to OLAW

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,
(b) (6)

(b) (6)

A3227-6L

Office of Laboratory Animal Welfare

OLAW

# Initial Report of Noncompliance

By: [redacted] (b) (6)

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

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

What happened?
Weaned mice put in cage w no food, 2 died, 2 monitored + died. Not seen on health check due to red light on in room.

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths: 4

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____