



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 6K)

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 August 4, 2021 letter reporting two instances of noncompliance with the PHS Policy on Humane 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 on two different studies mice failed to receive analgesics as required in the approved protocol. No adverse effects were observed in the mice due to not receiving the drugs.

The corrective actions consisted of counseling the laboratories to follow the protocol and requiring the staff to submit monthly analgesic logs to the Institutional Animal Care and Use Committee (IACUC). The laboratory staff members were retrained and the Principal Investigators provided preventive plans to the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. While OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy, we note that repeated incidents of not providing analgesia may once again indicate a programmatic problem which requires an institution wide solution. Ensuring prevention or reduction of pain/distress in laboratory animals is a key requirement of a compliant animal care and use program. 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



*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 two incidents found during the July Semi-annual inspections, which involved laboratories that did not provide analgesics as outlined in their IACUC-approved protocols. 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 OLAW regarding these incidents.

Species Involved: mice

Funding Sources: The two protocols were associated with the following funding sources: (Protocol 1) NIH: R37 AA019455-06A1; NIH: R01 DA042475-01; National Institute on Alcohol Abuse and Alcoholism: K99 AA027774-01; National Institute on Alcohol Abuse and Alcoholism: 1K99 AA027774-01A1; NINDS: R01 1NS102306 01 and Protocol 2) NIH: GM122491.

Incident Descriptions: Although no health concerns were noted in the animals, the incidents involved two laboratories that did not provide analgesics as outlined in their IACUC-approved protocols. The laboratories were reminded of the importance of following their approved protocols and both were asked to submit monthly analgesic logs for one year for the IACUC to review. The Principal Investigators (PIs) retrained their laboratory personnel and provided the IACUC with plans on how they would prevent reoccurrence.

At convened meetings held on August 25 and September 22, 2021, the IACUC discussed the incidents and the responses provided by the PIs. The IACUC

found the actions taken by the PIs addressed the Committee's concerns. The IACUC considers the incidents 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)



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? 7 mice

- 1) Mice didn't receive analgesic at the correct time per protocol.
- 2) Mice didn't get analgesic at interval approved.

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths:

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

Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____