



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

April 11, 2019

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

Dr. John F. Manning, Jr.  
Chief Operating Officer  
Vanderbilt University Medical Center  
(b) (4) Medical Center North  
11611 21<sup>st</sup> Avenue South  
Nashville, Tennessee 37232-2104

Dear Dr. Manning,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 28, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, following up on an initial telephone report on January 29, 2019. According to the information provided, OLAW understands that there was no documentation of the provision of analgesia to 40 mice following a craniotomy procedure. The Principal Investigator (PI) stated that the drugs had been given, that this was documented on the cage cards, but that the cards had been discarded.

The corrective actions consisted of the PI retraining the laboratory staff on documentation and records retention and requiring the laboratory's analgesic logs to be submitted to the Institutional Animal Care and Use Committee (IACUC) for one year. The IACUC accepted the PI's corrective actions.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Director of Animal Welfare



March, 28, 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 a laboratory that did not document analgesic administration as outlined in their IACUC-approved protocol. A preliminary report was filed by VUMC via phone 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:** Foundation, Endowment, and NIH funding. NIH Grant numbers: MH107435-01A1, MH100096 and M0044064

**Incident Description:**

On January 8, 2019, during the IACUC semi-annual inspection (SAI) it was found that post-operative administration of analgesia (Ketoprofen) was not documented on the analgesic log for approximately 40 mice that underwent a craniotomy procedure. The IACUC-approved protocol indicates that 72 hours of post-operative analgesia will be provided.

**IACUC Actions Taken and Corrective Plans:**

The information gathered by the Office of Animal Welfare Assurance (OAWA) at the SAI was brought to the IACUC at a convened meeting on January 23, 2019. The IACUC discussed the facts and voted to require that the Principal Investigator (PI) provide a plan to prevent recurrence, retrain the laboratory staff, and submit the laboratory's analgesic logs for review for one year beginning in February 2019.

**Implementation of Changes:** In correspondence dated January 24, 2019, the PI assured the IACUC that the analgesics had been given. The laboratory

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

personnel had recorded the analgesic post-operative dosing on the cage cards, then disposed of the cage cards at the end of the experimental procedure. The PI discussed the issue with laboratory personnel and provided training on appropriate methods for documenting and retention of analgesic records. The PI agreed to analgesic log review for one year.

At its convened meeting on February 27, 2019, the IACUC discussed the PI's response to the incident and found that the actions taken addressed the concerns and the PI had provided an appropriate plan to prevent reoccurrence of the issue. 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 Dr. Scott Bury at (b) (6) with any questions.

Sincerely,

(b) (6)

John P. 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  
Jeanne M. Wallace, DVM, DACLAM, Attending Veterinarian

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 10, 2019 11:59 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: VUMC Letters to OLAW A3227-01

Thank you for providing these reports (b) (6). We will send official responses 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:** Monday, April 01, 2019 3:39 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** VUMC Letters to OLAW A3227-01

Good Afternoon,  
Please find attached two letters. One is the update letter for case 5L.  
Let me know if you have any questions.  
Thanks,  
(b) (6)

(b) (6)





# Initial Report of Noncompliance

By: am

Date: 1/29/19

Time: 12:15

Name of Person reporting: Scott Bury  
 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?  
Craniothorax + no records of analgesia for 40 mice

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

Projected plan and schedule for correction/prevention (if known):   
Coversed on record keeping, use templates to record drugs

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY  
 Case #