



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

February 28, 2019

Re: Animal Welfare Assurance  
#A3227-01 (OLAW Case 50)

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 February 27, 2019 letter reporting an instance 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 December 17, 2018. According to the information provided, OLAW understands that mice failed to receive post-operative analgesics at the frequency outlined in the approved protocol.

The corrective actions consisted of retraining the laboratory staff on providing analgesics as described in the protocol and having the Principal Investigator provide monthly analgesic logs to the Institutional Animal Care and Use Committee. The laboratory will conduct the surgeries early in the day to ensure that staff is present to provide the analgesics.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Director of Animal Welfare



February 27, 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 analgesics not administered as approved in the protocol. A preliminary report was filed via phone with OLAW on December 17, 2018.

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

**Species Involved:** Mouse

**Funding Source:** NIH-Grant #'s: R01GM119197, R01GM121711 and K08GM123345

**Incident Description:**

During a Post Process Review (PPR) on November 7, 2018, a Post-Approval Monitor with the Office of Animal Welfare Assurance (OAWA) reviewed records that indicated that a laboratory performing a surgical procedure did not administer analgesia at the frequency approved in the IACUC protocol.

**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 December 12, 2018. The IACUC discussed the facts and voted to require that the Principal Investigator (PI) provide a plan to address the inconsistency of analgesic administration. The PI will also be required to submit the laboratory's analgesic logs monthly for one year.

**Implementation of Changes:**

In correspondence dated December 20, 2018, the PI assured the IACUC that all laboratory personnel have been retrained on the appropriate administration of analgesics as approved in the protocol. As a further

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measure the laboratory will schedule the experiments earlier in the morning to ensure that a laboratory member is available during the analgesic administration dosing timeframe.

At its convened meeting on January 23, 2019, the IACUC discussed PI's response to the incident and found these actions addressed the concerns and 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 F. 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, February 27, 2019 2:30 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Letters from VUMC A3227-01

Thank you for providing these reports. I will forward them to Dr. Wolff who will send official responses.

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:** Wednesday, February 27, 2019 12:07 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Letters from VUMC A-32227-01

Good Morning,

Please find attached three letters from the Vanderbilt IACUC. One of the three is a follow-up letter with more information on the #5R incident. Let me know if you have any questions.

Regards,

(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: aw

Date: 12/17/18

Time: 3:50

Name of Person reporting: Scott Bury  
 Telephone #: (b) (6)  
 Fax #: [REDACTED]  
 Email: [REDACTED]

Name of Institution: Vanderbilt U  
 Assurance number: A3227

Did incident involve PHS funded activity? Yes  
 Funding component: [REDACTED]  
 Was funding component contacted (if necessary): [REDACTED]

What happened?

Burn study. Analgesics not given at proper interval

Species involved: mice  
 Personnel involved: [REDACTED]  
 Dates and times: [REDACTED]  
 Animal deaths: [REDACTED]

Projected plan and schedule for correction/prevention (if known): [REDACTED]

PI on enhanced reporting re: analgesic use

Projected submission to OLAW of final report from Institutional Official: [REDACTED]

OFFICE USE ONLY

Case # [REDACTED]