



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

November 13, 2018

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

Dr. John F. Manning, Jr.
Chief Operating Officer
Vanderbilt University Medical Center
D-3300 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 November 12, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Vanderbilt University, following up on an initial telephone report on October 11, 2018. According to the information provided, OLAW understands that two additional pigs, above the number approved on the protocol, had been transferred from another protocol. The laboratory staff ignored the procurement system warning, obtained the two pigs, and used them in accordance with the protocol. The Division of Animal Care (DAC) failed to intervene and prevent ordering and use of the pigs.

The corrective actions consisted of amending the protocol to include additional animals and having the Principal Investigator verify the number of animals approved on the protocol before ordering additional ones. The DAC placed a warning in the animal ordering system to alert users that the approved number of animals is approaching and a complete stop when the number is reached.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director of Animal Welfare
Robert Gibbens, D.V.M., USDA-APHIS-AC



November 12, 2018

*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 animals received above the number approved by the IACUC. A preliminary report was filed by VUMC via phone with OLAW on October 11, 2018.

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

Species Involved: Swine

Funding Source: Commercial/Industry

Incident Description:

During a Post Process Review (PPR) on August 3, 2018, a Post-Approval Monitor (PAM) with the Office of Animal Welfare Assurance (OAWA) found that the laboratory had ordered and received two more animals via a protocol-to-protocol transfer than were approved on the protocol. The report indicated that research staff had ignored a procurement system warning that their approved animal balance was zero. The PAM verified that the animals were used and euthanized according to IACUC-approved procedures.

Further investigation into the incident also noted that the Division of Animal Care (DAC) failed to prevent the laboratory from ordering and receiving these two animals.

IACUC Actions Taken and Corrective Plans:

The Principal Investigator (PI) submitted an amendment to add animals and provided a plan to prevent this type of error in the future. The PI response dated August 8, 2018, indicated that the PI would verify the number of animals on the protocol before placing any orders.

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tel 615.322.0230
fax 615.343.7286
john.manning@vanderbilt.edu

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 13, 2018 6:51 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letters from VUMC A-3227-01

Thanks for these reports, (b) (6) I will send responses soon.
Axel Wolff

From: (b) (6)
Sent: Monday, November 12, 2018 3:11 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Bury, Scott Douglas <scott.d.bury@vumc.org>
Subject: Letters from VUMC A-3227-01

Good Afternoon,
Please find attached the final letters from VUMC.
Let me know if you have any questions.
Regards,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: aw

Date: 10/10/18

Time: 12:00

Name of Person reporting: Scott Barry

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?

10 preapproval, 2 more ordered despite returning

Species involved: Pig

Personnel involved:

Dates and times:

Animal deaths:

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

Adjust electronic system so animals are not ordered
Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____