



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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

January 15, 2019

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

Dr. John F. Manning, Jr.  
Chief Operating Officer  
Vanderbilt University Medical Center  
D-3300 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 January 7, 2019 letter reporting the suspension of an animal activity at Vanderbilt University Medical Center, following up on an initial telephone report on November 16, 2018. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action in response to a post approval monitoring review which found unapproved breeding and genotyping of mice, genotyping 28 day old mice without anesthesia, using non-sterile gloves and instruments for survival surgery, and identifying 10 cages of mice with wound dehiscence.

The immediate action taken upon discovery consisted of repairing the incisions. In addition to suspending the protocol, the IACUC suspended the animal use privileges of the Principal Investigator (PI) and laboratory members. The PI responded to the IACUC and stated that the breeding mice were transferred to another PI, mouse genotyping will be performed under anesthesia, the protocol was amended, the laboratory staff was retrained on analgesia documentation, and sterile gloves and instruments will be used during survival surgery. The IACUC accepted the PI's plan, reinstated the protocol, and will have a veterinarian or member of Office of Animal Welfare Assurance monitor all surgical procedures, animals, and records. The PI and staff were counseled and retrained.

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



January 7, 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.c, 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 suspension of a protocol. A preliminary report was filed via email with OLAW on November 20, 2018.

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

**Species Involved:** Mouse

**Funding Source:** Departmental

**Incident Description:**

During a Post Process Review (PPR) on October 16, 2018 a Post-Approval Monitor with the Office of Animal Welfare Assurance (OAWA) identified several issues of non-compliance including breeding and genotyping of mice while not approved under the protocol, genotyping of animals at 28 days of age without anesthesia, use of an unapproved analgesic, use of non-sterile gloves for survival surgery, and not sterilizing instruments prior to a survival surgery. The IACUC also received a report from the Division of Animal Care (DAC) Veterinary staff that indicated that on November 2<sup>nd</sup>, seven cages of mice had abdominal surgical site dehiscence. Also, on November 3<sup>rd</sup>, another three cages of mice were identified with surgical site dehiscence. The laboratory responded quickly on November 2<sup>nd</sup> to repair the incisions, while the response to the DAC on November 3<sup>rd</sup> took several hours.

**IACUC Actions Taken and Corrective Plans:**

The information gathered by OAWA during its investigation was brought to the IACUC at a convened meeting on November 14, 2018.

After deliberation of these incidents by a quorum of members, the IACUC voted to suspend the protocol, as well as to suspend the Principal Investigator (PI) and three of the laboratory staff that assisted in the survival surgical procedure from performing any survival surgical procedures at the

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institution. The IACUC voted to require that the PI provide a petition for reinstatement of the protocol and attend a convened IACUC meeting before the reinstatement would be considered. The IACUC required that the petition include:

1. A plan that addresses how the PI would correct the items identified during the Post-Process Review. This plan must also include how the laboratory will prevent these types of non-compliance issues in the future, how the laboratory will monitor animals after a survival surgical procedure, and how the PI will conduct and/or monitor communication with their staff and DAC or IACUC when animal health issues are identified.
2. Confirmation from the PI that they have discussed the above-mentioned non-compliance concerns and the plan to prevent reoccurrence with the laboratory staff.
3. Completion by the PI and pertinent laboratory staff of the following Vanderbilt Animal Care and Use Program courses: 1) Ethics and Animal Care and Use Orientation, and 2) Aseptic Survival Surgery Curriculum (online and in-person modules).

**Implementation of Changes:** In correspondence dated December 1, 2018, the PI confirmed:

1. the breeding mice were transferred to another PI (no further breeding is planned).
2. all future genotyping on mice will be performed under anesthesia.
3. the protocol was amended to address the required clarification from the PPR.
4. the laboratory staff were retrained on the appropriate recording of analgesics.
5. sterile gloves and appropriately sterilized instruments will be used for all survival surgeries.
6. both the PI and staff completed the Ethics and Animal Care and Use Orientation course, and the Aseptic Survival Surgery Curriculum on December 10<sup>th</sup>.
7. all the non-compliant concerns and the prevention plan had been discussed with the laboratory staff. The PI also indicated that any new staff would take the Aseptic Survival Surgery Curriculum before performing surgeries.

At its convened meeting on December 12, 2018, the IACUC and the PI discussed the PI's response to the incident. The IACUC found the PI addressed the concerns and provided an appropriate plan to prevent reoccurrence of the issues, and therefore voted to reinstate the protocol. The IACUC considers the incident closed, with the following stipulations: The PI must notify the OAWA before each of the surgical procedures so that a member of OAWA and/or the DAC Veterinary staff might observe the

surgical prep, the surgery and/or evaluate the animals and records after surgery.

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

(b) (6)

(b) (6)

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(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: an

Date: 11/16/18

Time: 3:40

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? No

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Species involved: Mice

Personnel involved: \_\_\_\_\_

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

*Suspended protocol, P.H.U. review found breeding and genotyping mice without approval, tail snip 28 days without analgesia, using unapproved analgesic, not sterile gloves during survival surgery, nonsterilized instruments, 10 cages of mice w/ deliriousness.*

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

*Retrain PI + staff*

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_