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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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

October 10, 2018

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

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 September 26, 2018 letters reporting several serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Vanderbilt University, following up on an initial telephone report on the same day. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

1) Fourteen mice died on three separate days due to being separated into cages without food. The animals had been separated by research staff and the problem was not identified by animal care staff during the daily health checks.

2) Ten mice died after their cages of mice had been tagged for euthanasia and no food was provided. The problem was not identified during the daily health checks and it was determined that a shortage of animal caretakers contributed to the problem.

Corrective action: Each laboratory involved in separating animals into cages without food was retrained. A plan was developed for recruiting and retaining additional animal care staff and the animal caretakers were retrained.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. While OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, we stress the importance of swiftly and aggressively addressing programmatic problems. Having animals die from lack of food and water in multiple laboratories over multiple time periods constitutes a programmatic problem and serious animal welfare concern which requires a program wide preventive action. Should additional food/water incidents occur (in addition to those reported in cases A3227-5F and 5H), OLAW will place Vanderbilt University on an enhanced reporting schedule to monitor the success of proposed corrective measures. Thank you for keeping OLAW apprised on these matters.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director of Animal Welfare

VANDERBILT UNIVERSITY MEDICAL CENTER

September 26, 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
Species Involved: Mouse
Funding Sources:
Incident 1: NIH 1R01Gm118300-01 and other agencies.
Incident 2: NIH MH107435-01A1, NIH MH100096, NIH M0044064
Incident 3: NIH: RO1 CA1322898; GM 50526; GM 070902; R35 CA197571; and F32 CA213794
Incident 4: NIH: CA77955
Incident 5: Departmental
Incident 6: Departmental

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 six separate instances of mice found without food. Preliminary reports were filed via phone with OLAW on May 30, 2018 (incidents 1 and 2) and July 26, 2018 (incidents 3-6).

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

Incident Description:
On May 16, 2018, the Office of Animal Welfare Assurance (OAWA) received a self-report from the Division of Animal Care (DAC), regarding two separate incidents where animals were found dead without food in the cages (incidents 1 and 2). Separately, on June 21, 2018, the OAWA received a second self-report from the DAC regarding four additional incidents where animals were found dead without food and/or water in the cages (incidents 3-6).

Incident 1: The report indicated that on April 16, 2018, the DAC found two cages of dead mice (seven animals total) without food in the cages. These animals were experimentally naïve and had not been handled by the laboratory staff. The DAC technicians failed to find that the cages were without food during the daily health checks.

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john.manning@vanderbilt.edu

Incident 2: The report indicated that on May 4, 2018, the DAC found three cages of animals without food, with one animal found dead. The Facility Veterinarian was notified, and supportive care was provided to the remaining animals, however two additional animals died (three total). The laboratory staff had separated out these cages on April 29 and did not provide any food for the new cages. Subsequently, the DAC technicians failed to find that the cages were without food during the daily health checks.

Incidents 3-5:
The second report letter indicated that the DAC found a total of 4 cages of animals without food and/or water on May 21 (two cages), 28 (one cage) and 29 (one cage). Fourteen out of fifteen animals were found dead in those four cages. For all three incidents, the laboratory staff had separated out these cages and had forgotten to add food and/or water. Again, the DAC technicians did not discover that the cages were without food and/or water during the daily health checks.

Incident 6:
Additionally, the DAC reported in the second self-report letter that on June 2 three cages of animals marked for euthanasia were found without food, and all ten animals were found dead. The DAC technicians responsible for these cages again failed to find that these cages had no food.

In their response included in both reports, the DAC indicated that refresher training was provided to all relevant personnel regarding completion of daily health checks. The DAC also reported that significantly reduced staffing levels coupled with increased room observations and cage change assignments were contributing factors to the incidents.

IACUC Actions Taken and Corrective Plans:
The IACUC reviewed the first DAC self-report at a convened meeting on May 23, 2018. The IACUC discussed the report and voted to require that the DAC provide a detailed staffing plan to address the shortage of animal care staff. Regarding incident 2, the IACUC requested the PI provide a plan to address the incident and prevent further recurrence. The committee voted that the incident was reportable to OLAW.

The IACUC discussed the second report letter at a convened meeting on July 25, 2018. The committee determined that in the instances involving PI failure to provide food and/or water (incidents 3-5), that the IACUC send a letter to each of the PIs instructing them to retrain their laboratory staff and to verify that they have provided food and/or water for all cages when separating the animals. The committee voted that the incidents were reportable to OLAW.

Implementation of Changes:

(b) (6)

(b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 01, 2018 9:44 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: VUMC Final Letters A-3227 01

Thank you for providing these final 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

From: (b) (6)
Sent: Friday, September 28, 2018 11:16 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: VUMC Final Letters A-3227 01

Good Morning,
Please find attached four final letters from VUMC.
Let me know if you have any questions or need anything further.
Regards,
(b) (6)

(b) (6)

A3227-5H

Initial Report of Noncompliance

By: RW

Date: 9/26/18 Time: 1:00

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?

3 separate situations
1) 7 mice dead the morning food given after weaning. Cage taken
2) 3 mice dead after weaning, no food, not caught
3) 4 mice dead no food after weaning, not caught
4) 7 mice to be genotyped, found not on cage + mice not fed, died

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

Projected plan and schedule for correction/prevention (if known): _____
Not enough staff to cover all the animals, trying to hire more staff.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____