



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 10, 2018

Re: Animal Welfare Assurance
#A3281-01 [OLAW Case 2B]

Francis L. Macrina, PhD
Vice President for Research
Virginia Commonwealth University
Biotech One, (b) (4)
PO Box 980568
Richmond, VA 23298-0568

Dear Dr. Macrina,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 9, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Virginia Commonwealth University. According to the information provided, OLAW understands that a mouse died due to lack of food and water. The animal was found in an empty food hopper and it was assumed that a laboratory member sorted mice and inadvertently put the cage with the mouse back on the rack. The individual responsible was not identified.

The corrective actions consisted of counseling all investigators using the room to carefully check all cages they handled to ensure the presence of food, to ensure no water is leaking, and that all animals are in good condition. All used cages are to be put on the dirty cage shelf for animal care staff to remove to prevent cross-cage contamination. All manipulated cages should be checked by research staff before leaving the room.

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 on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Amy Chuang, Assoc. Dir. for Animal Research

A3281-213



VCU

Office of Research and Innovation

April 9, 2018

Axel V. Wolff, M.S., D.V.M., Deputy Director
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Francis L. Macrina, PhD
Edward Myers Professor of Dentistry and
Vice President for Research and Innovation

VCU Animal Welfare Assurance number D16-00180 (A3281-01)

Dear Dr. Wolff:

Virginia Commonwealth University, in accordance with Assurance D16-00180 (A3281-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding lack of water and food resulting in the death of a single mouse. This incident was reported to you on April 4, 2018 via a telephone call by Ms. Amy Chuang, Director of Animal Care and Use Program, Office of Research Subjects Protection (ORSP).

Description of Incident:

On March 20th, Division of Animal Resources (DAR) animal care staff reported one cage containing one mouse found dead due to lack of food/water during morning health observations. The cage was a previously clean cage that had been stored in the room for DAR and researchers to use. The mouse was found inside of the empty food hopper. These extra cages are typically stored with no food or water/hydropac containers in the room and they are placed backwards on an IVC rack away from occupied cages to clearly differentiate them from the occupied cages. The veterinarian evaluated the mouse and the necropsy report indicated that the animal died from dehydration. Since we could not identify which investigator the animal belonged to, we notified all seven investigators sharing this room. We believe it is likely that this animal was left inside the cage by accident while one of research staff sorted the animals and placed the cage back onto the IVC rack with the other clean cages.

Corrective action plan:

- (1) All investigators and lab personnel in this room were notified on March 30th and were instructed to follow the procedures below:
 - All lab personnel should look closely at every cage they have handled before they leave the animal room for the day, including both the occupied cages and the empty, dirty cages they have placed onto the room's dirty shelf rack for DAR to remove. They should make sure that every cage has a full food hopper and adequate water in the Hydropac,

that the water is not leaking, that no animals have been left in the food or water hopper, and that all animals appear to be in good condition.

- Cages that have been used for temporary animal movement (e.g., using a clean, empty cage to sort mice) should be put onto the dirty cage shelf for DAR to remove. This includes cages that have only been used for a moment - once an animal has been put into a clean cage for any length of time, the cage is considered to be used. Placing this cage back with clean cages will lead to cross-cage contamination, which violates the most basic concept of aseptic procedure and could place the animals and work of all researchers in the room in danger. Practices such as this are primary methods by which mouse pathogens spread among researchers.

- (2) The investigator and lab personnel were informed to ensure animals must not be left without food and water. It was suggested that they develop a habit of visually checking all cages they have handled before leaving the animal room.

We regret that this incident occurred. Following our detailed investigation, we have deployed specific corrective actions to enhance our program and to minimize future occurrences. The IACUC will be advised of the above corrective actions at the next full committee meeting on April 11th.

We appreciate your consideration of VCU's efforts to minimize future occurrences. VCU remains committed to animal welfare and recognizes its ethical responsibilities in ensuring the welfare of research animals and complying with the *PHS Policy on the Humane Care and Use of Laboratory Animals*.

Sincerely,

(b) (6)

Francis L. Macrina, Ph.D.
Edward Myers Professor of Dentistry
& Vice President for Research and Innovation

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 09, 2018 1:32 PM
To: Kuei-Lan Chuang
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Thank you for this letter, Amy. I will send a response soon.
Axel Wolff

From: Kuei-Lan Chuang [mailto:kchuang@vcu.edu]
Sent: Monday, April 09, 2018 12:54 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Francis Macrina <macrina@vcu.edu>; (b) (6)@vcu.edu
Subject: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Dear Dr. Wolff,

Attached please find the follow-up reporting letter signed by Dr. Macrina, VCU Institutional Official. The incident was reported to you by phone on April 4th. The written report includes a detailed explanation of the incident and actions taken by VCU.

We have reviewed this incident thoroughly and deployed specific corrective actions designed to enhance our animal program and to prevent future occurrences. We appreciate your consideration and VCU recognizes its responsibilities to comply with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Guide, and also remains committed to animal welfare.

Should you have any questions regarding this matter, please do not hesitate to contact me at (b) (6) or email to: kchuang@vcu.edu.

Best Regards,

Amy Chuang

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Amy

Amy Chuang, M.S., RQAP-GLP, CPIA
Director of the Animal Care and Use Program
Office of Research Subjects Protections (ORSP)
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Animal Research website: <https://www.vcu.edu/research/acup/index.htm>

Animal Care and Use Program Blog: <http://wp.vcu.edu/acup/>