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

June 26, 2019

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

Dr. P. Srirama Rao
Vice President for Research and Innovation
Virginia Commonwealth University
Biotech One, (b) (4)
PO Box 980568
Richmond, VA 23298-0568

Dear Dr. Rao,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 25, 2019 letter reporting two serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Virginia Commonwealth University, following up on an initial telephone report on June 6, 2019. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

1) Two mice died and three were lethargic due to lack of water caused by food pellets preventing correct seating of the water bottle, putting it out of reach of the mice. The weekend animal caretaker did not call the veterinary staff or provide food/water support.

Corrective actions: The next day the primary caretaker placed DietGel and HydroGel in the cage for the surviving mice which recovered. The weekend caretaker was counseled and retrained on calling the veterinarian and providing supportive care. The entire animal care staff was also retrained on these topics.

2) One mouse died and two were lethargic due to lack of water caused by an improperly placed water bottle, which prevented access by the mice. The bottle had a shorter sipper tube which contributed to the problem.

Corrective actions: The two mice were euthanized. The animal caretaker was counseled and retrained on which length of sipper tube to use and all caretakers were informed and retrained on this as well. The research staff was also informed about which size tube should be used and with which animals. All staff handling cages was informed that bottles may shift and that proper bottle placement should be verified.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a recurrence of these problems. 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
Director for the Animal Care and Use Program

VCU
Office of Research and Innovation

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P. Srirama Rao, PhD
Vice President for Research and Innovation
Professor of Microbiology and Immunology,
School of Medicine

June 25, 2019

Axel V. Wolff, M.S., D.V.M.
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Suite 2500, MSC 6910, 6700B Rockledge Drive
Bethesda, MD 20892
(301) 496-7163

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 two incidents described below. This first incident involved a water bottle issue resulting in the deaths of two mice. The second incident involved the use of the wrong sipper tube in a water bottle resulting in the death of one mouse plus two mice subsequently euthanized. Both incidents were reported to you on June 6, 2019 via a telephone call by Ms. Amy Chuang, Director of Animal Care and Use Program, Office of Research and Innovation.

Description of Incident #1:

On Sunday, May 19th the Division of Animal Resources (DAR) animal weekend caretaker completed the paperwork indicating that two of five mice appeared lethargic. On Monday, the primary caretaker found that these two animals had died and been cannibalized. The remaining three mice were lethargic so the primary caretaker placed DietGel and HydroGel into the cage. They appeared to be recovering well after close monitoring. After the veterinarian examined the animals & the cage, it appears that food pellets had fallen into the water bottle side of the wire bar feeder. At some point, the food blocked the end of the sipper from sliding through the sipper slot. As a result, the animals could not reach water. This condition can form when a cage is roughly handled so that food and water are jostled or if food is allowed to overflow into the water bottle side of the hopper during cage change. The investigation revealed that the weekend animal caretaker failed to contact the veterinary staff and did not provide support (wetted food, DietGel or HydroGel) for the lethargic animals, resulting in the deaths of the animals.

Corrective action plan:

(1) The DAR animal weekend caretaker involved in this incident received individual counseling and retraining on reporting clinical health issues to veterinary staff and the addition of cage supplements (e.g., wetted food, HydroGel, DietGel) to cages for support. Documentation of this retraining was provided to the Director of Animal Care and Use Program and recorded in DAR's training file.

(2) In order to minimize the possibility of a similar incident occurring in the future, at the June 5th DAR staff meeting all DAR staff with animal husbandry responsibilities were apprised of this incident and reminded to "report clinical health issues to veterinary staff". They were also reminded that they are authorized and should feel free to put wetted food, DietGel and/or HydroGel onto the cage floor if animals are lethargic/dehydrated, or at any time they feel a sick or injured animal could benefit. Documentation and description of this meeting were provided to the Director of Animal Care and Use Program and will be maintained in DAR's training folder.

Description of Incident #2:

During morning health observation on Friday May 31st, a cage was found to have one dead mouse and two mice that appeared to be lethargic. The primary caretaker found that the water bottle was not properly placed, so the animals could not reach water. The investigative staff was notified and requested to euthanize the remaining two mice. The caretaker reported that the end of the sipper tube appeared to have just caught on the wire bar, keeping it from sliding into the cage. This cage contained a water bottle with a 1.5-inch sipper tube. It appears that the bottle in the cage shifted backwards, probably when the rack was moved, and resettled against the feeder rather than through the sipper slot due to the shortness of the sipper tube. As a result, the animals were not able to access water. The investigation determined that if a 2.5- inch sipper tube had been used, the bottle would not have been able to shift out of position.

Corrective action plan:

(1) The DAR animal caretaker involved in this incident received individual counseling and retraining on when to use the shorter and longer sipper tubes. Documentation of this retraining was provided to the Director of Animal Care and Use Program and recorded in DAR's training file.

(2) In order to minimize the possibility of a similar incident occurring in the future, at the June 5th DAR staff meeting all DAR staff with animal husbandry responsibilities were apprised of this incident, including an emphasis on when to use shorter and longer sipper tubes. The shorter sipper tubes (1.5 inch) are used with rats and with mice that are older than 3 months of age. For younger and/or smaller mice, the 2.5-inch sipper tubes should be used. Documentation and description of this meeting were provided to the Director of Animal Care and Use Program and will be maintained in DAR's training folder.

(3) The research group will be made aware that short sipper tubes should not be used for younger and/or smaller mice. In addition, everyone who handle cages will be reminded that some bottle types may shift during cage handling, necessitating care when moving racks and verification of proper bottle placement after placing the cages back onto the rack.

Both research protocols involved are PHS funded.

We regret that these incidents 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 their next full committee meeting.

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)

P. Srirama Rao, PhD
Vice President for Research and Innovation
Professor of Microbiology and Immunology, School of Medicine

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 26, 2019 7:06 AM
To: Kuei-Lan Chuang
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Thanks for this report, Amy. I'll send a reply shortly.
Axel Wolff

From: Kuei-Lan Chuang <kchuang@vcu.edu>
Sent: Tuesday, June 25, 2019 4:55 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Srirama Rao <psrao@vcu.edu>; (b) (6) [redacted]
Subject: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Dear Dr. Wolff,

Attached please find the follow-up letter signed by Dr. Rao, VCU Institutional Official. These two incidents were reported to you by phone on June 6. The written report includes a detailed explanation of these incidents and actions taken by VCU IACUC.

We have reviewed these two incidents 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) [redacted] or email to: kchuang@vcu.edu.

Best Regards,

Amy Chuang

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Amy

Amy Chuang, M.S., RQAP-GLP, CPIA
Director for the Animal Care and Use Program (ACUP)
Office of Research and Innovation
Virginia Commonwealth University
Box 980568
800 E. Leigh St., (b) (4) [redacted]
Richmond, VA 23298
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kchuang@vcu.edu

Animal Research website: https://research.vcu.edu/secure/acup/index.htm
Animal Care and Use Program Blog: http://wp.vcu.edu/acup/

A3281-2G

Initial Report of Noncompliance

By: AM

Date: 6/6/19 Time: 4:00

Name of Person reporting: AMY CHEUNG
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: VIRGINIA Commonwealth U
Assurance number: A3281

Did incident involve PHS funded activity? _____
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
1) 2 mice lethargic, not reported to vet + died. Water bottle was pushed up by feed
2) 1 mouse dead, 2 lethargic, Water bottle had wrong length sipper tube

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

Projected plan and schedule for correction/prevention (if known): _____
1) Counsel, retrain, Hands on + group training
2) Vet examined mice but Lab requested euthanasia, Train staff to use correct sipper tube Check tubes

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____