



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) 480-3387

October 12, 2022

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

Dr. P. Srirama Rao
Vice President for Research and Innovation
Virginia Commonwealth University
800 East Leigh St.,
Biotech One, (b) (4)
PO Box 980568
Richmond, VA 23219

Dear Dr. Rao,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 7, 2022 letter reporting a serious deviation 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 September 29, 2022. According to the information provided, OLAW understands that three mice died due to lack of water caused by a clogged sipper tube. The rubber seal had dry rotted and caused an air lock. Visualization of the mice was difficult due to presence of an enrichment device and therefore not identified promptly.

The corrective actions consisted of retraining the animal caretakers on recognizing the clinical signs of dehydration in rodents, developing a checklist with health items which require contacting the veterinarian, training staff on the checklist, evaluating all sipper tubes and replacing defective ones, and having caretakers pull out cages for examination during the daily health checks. Research staff must now check cages for the presence of food/water following manipulations.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a 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. As Institutional Official, please remember to sign or initial all noncompliance reports to OLAW.

Sincerely,

(b) (6)

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

cc: IACUC Chair

(b) (6)

A3281-25



VCU

Office of Research and Innovation

October 7, 2022

Axel V. Wolff, M.S., D.V.M.,
Deputy Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892
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Office of Research and Innovation
Animal Care and Use Program
Virginia Commonwealth University
BioTechnology Research Park
800 East Leigh Street, (b) (4)
Box 980568
Richmond, VA 23298-0568

(b) (6)
IACUC@VCU.EDU

(b) (6)

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 the death of three mice due to a water bottle issue (mechanical failure), which I discussed and reported to you via a telephone call on September 29, 2022.

Description of Incident:

During afternoon observations on September 22nd, the Division of Animal Resources (DAR) animal care staff reported three mice were found dead. The veterinary staff was notified immediately. The cage had a full food hopper and a full water bottle with a small air bubble. The water sipper tube appeared to be partially clogged. When the sipper ball was pressed only a very small amount of water was obtained. The bottle had small pieces of rubber in it (degraded green pieces from the sipper), which likely contributed to the clogging. There was a vacuum-lock present when the sipper cap was removed from the bottle. It was determined that the water bottle was clogged due to dry rotting of the rubber seal and air locked so that the animals could not obtain water. It is very hard for the husbandry staff to notice the water bottle issue since the food/water levels were fine during their daily observation. In addition, the animals were found in the back portion of the cage; the front of the cage was dominated by a red plastic "Mouse House", which is a red tinted polycarbonate enrichment device often placed in cages to help minimize aggressive tendencies, so they are able to "hide" within the structure. DAR husbandry staff do not currently move the caging during routine health observations, so it is possible to overlook signs of dehydration.

Corrective action plan:

- (1) All DAR staff were trained on signs of dehydration in rodents (skin wrinkling/tenting, sunken eyes/facial features/sides, lethargy, and lack of balance) during their full staff meeting on September 28th. The training was offered by one of the veterinarians. Documentation of this training will be provided to the Director of Animal Care and Use Program and recorded in DAR's training file.
- (2) The veterinary staff will create an urgent issue description list to aid staff in determining when an animal health issue may require a call to vet staff for immediate examination. This list will include signs of dehydration. The vet staff will determine which DAR SOP would be the most appropriate to contain this information. Once the SOP has been finalized, all DAR staff will be trained.
- (3) DAR management is evaluating all of these types of sippers for signs of dry rot and replacing them as needed.
- (4) A long-term plan: DAR husbandry staff will transition to once-daily comprehensive health observations as of October 10th for one of our animal facilities. This practice will be introduced to the other animal facilities in phases to ensure as smooth a transition period as possible for each area. Each cage will be gently pulled out as far as needed for the staff member to be able to clearly see food and water levels, cage bedding, and animals. Cages will not be entirely removed from their slots unless necessary to evaluate the cage or animals more closely. Research personnel will be required to double-check every cage they have handled before they leave the animal room, to ensure that they have filled every food hopper and water bottle (leaving a small air gap to allow the water to move) and verified that every bottle is functioning properly, and verified that the animals appear as healthy as possible.

Animals involved in this incident are related to the PHS-funded research. After a review of direct costs associated with the procurement, care, and use of animals, the monetary impact of the noncompliance is considered insignificant, and as such, it was not necessary to make an adjustment to the grant.

We regret that this incident occurred. Following our detailed investigation, we have deployed specific corrective actions to enhance our program and 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.

Axel V, Wolff, M.S. D.V.M.
October 7, 2022
Page 3

Sincerely yours,

 (b) (6)

(On behalf of Dr. P. Srirama Rao)

McCoy, Devora (NIH/OD) [E]

From: [REDACTED] (b) (6)
Sent: Friday, October 7, 2022 10:57 AM
To: Wolff, Axel (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Srirama Rao; [REDACTED] (b) (6)
Subject: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)
Attachments: OLAW letter FNL 10.7.2022.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Wolff,

Attached please find the follow-up noncompliance letter submitted by me on behalf of VCU's Institutional Official, Dr. Rao (cc on this email). I reported the preliminary information to you by phone on 9/29. The written report includes a detailed explanation of the situation and actions taken by VCU IACUC.

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 [REDACTED] (b) (6) or email: [REDACTED] (b) (6)

Sincerely,

[REDACTED] (b) (6)

[REDACTED] (b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 7, 2022 11:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Good morning (b) (6)

Thank you for sending us this final report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Friday, October 7, 2022 10:57 AM
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)
Subject: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

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Should you have any questions regarding this matter, please do not hesitate to contact me at (b) (6)

Sincerely,

(b) (6)

(b) (6)



A3281-2S



Initial Report of Noncompliance

By: (b) (6)

Date: 9/29/22

Time: 1:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: VCU

Assurance number: A3281

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

3 mice dead, water tube plugged

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Changing monitoring procedures

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____