



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

May 17, 2023

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

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 May 12, 2023 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 two mice died and one was lethargic due to dehydration. The Hydropac valve had become displaced after placement in the cage which prevented access to water by the mice. The daily health check did not identify the problem with the valve or the decline in the health of the animals.

The immediate action taken upon discovery consisted of treating the surviving mouse which subsequently recovered. The animal caretakers involved were retrained on the conduct of daily health checks and all caretakers were retrained on use of the Hydropac system.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and to 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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

(b) (6)

A3281-2U



VCU

Office of Research and Innovation

May 12, 2023

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
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Richmond, VA 23298-0568
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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 two mice and one lethargic mouse due to dehydration (displacement of the Hydropac lixit), which I discussed and reported to you via a telephone call on May 10, 2023.

Description of Incident:

While working in the animal room the afternoon of April 24, one cage was found to have two dead adult mice and one lethargic mouse that appeared dehydrated. The investigator and veterinary staff were notified immediately. The lethargic mouse was offered wetted food and diet gel and was recovered within 24 hours. The investigation revealed that the Hydropac valve became displaced after it was originally placed into the cage, resulting in the animals having no access to the water lixit. During daily observation, lixit displacement was not obvious. However, the DAR husbandry caretaker did not recognize the declining health of the mice in the cage during comprehensive observations over the weekend and the following Monday morning, contributing to the situation.

Axel V, Wolff, M.S. D.V.M.
May 12, 2023

Corrective action plan:

- (1) The DAR husbandry staff members involved in this incident have received refresher training on proper health observation procedures, with emphasis on taking sufficient time to make sure they have seen all cage elements, by the DAR Assistant Director of Program Development. Documentation of this retraining will be provided to the Director of the Animal Care and Use Program.
- (2) In order to minimize the possibility of a similar incident occurring in the future, all DAR staff with animal husbandry responsibilities were instructed to verify that each Hydropac cage has a visible lixit protruding into the cage from the water hopper during comprehensive daily health observations. On May 8, documentation and description of this meeting received during the 4/26/2023 staff meeting was provided to the Director of Animal Care and Use Program as well as maintained in DAR's training folder.

The animals involved in this incident are related to a PHS-funded research project. However, 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*.

Sincerely yours,

(b) (6)



(On behalf of Dr. P. Srirama Rao)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 15, 2023 11:18 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 for case A3281-2U and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Friday, May 12, 2023 2:03 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)
Subject: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

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 May 10th. 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 (b) (6) or email: (b) (6)

Sincerely,

(b) (6)

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(b) (6)



A3281-2U

Initial Report of Noncompliance

By: (b) (6)

Date: 5/10/23

Time: 8:00

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

Name of Institution: VIRGINIA COMMONWEALTH U
Assurance number: A3281

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

What happened?

Several mice impacted from lack of water due to improperly placed lipit in water bag (Hydrozac)

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths: 2

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

Retrain - Have caretakers carefully put lipits in bags

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____