

#### DEPARTMENT OF HEALTH & HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

February 23, 2022

Office of Laboratory Animal Welfare

Bethesda, Maryland 20892-6910

6700B Rockledge Drive, Suite 2500, MSC 6910

Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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

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 February 15, 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 January 27, 2022. According to the information provided, OLAW understands that a mouse died and three others were lethargic due to lack of food. A laboratory staffer had weaned the mice and failed to provide food and the problem was not noted during the daily health checks conducted by husbandry staff.

The immediate action taken upon discovery consisted of providing diet gel to the surviving mice, which responded well. The corrective actions consisted of counseling and retraining the laboratory staffer responsible as well as the other laboratory staff, counseling the animal care staff to carefully check all cages for food/water, reassigning husbandry staff to ensure adequate staffing, reassigning some husbandry duties to allow adequate time for health checks, updating the investigator training to include information on checking cages for food/water, and reminding all investigators to check cages for food/water after handling the cage or weaning.

Based on its assessment of this explanation, OLAW understands that measures have been implemented 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 and on conveying the message that all staff involved with animals are responsible for animal well-being. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



## Office of Research and Innovation

February 15, 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 (301) 496-7163 Office of Research and Innovation Animal Care and Use Program Virginia Commonwealth University BioTechnology Research Park 800 East Leigh Street, Suite 3000 Box 980568 Richmond, VA 23298-0568 (804) 828-6587,Fax: (804) 827-1448 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 one mice due to lack of food. I have discussed and reported to you via a telephone call on January 27, 2022.

#### Description of Incident:

On Sunday January 16th, the Division of Animal Resources (DAR) animal care staff reported two cages without food. One of four was found dead in one cage; the other three were lethargic. There were no dead in the second cage but all four were lethargic. DAR caretaker provided diet gel to the floor of each cage immediately for the remaining animals. It was noted in subsequent observations that the animals were responding well to the gel. Veterinary staff were notified immediately. On January 18<sup>th</sup>, the lab staff member indicated on the cage cards was contacted and confirmed these animals were newly weaned on January 12<sup>th</sup>. The investigation revealed that the lab staff member who handled the cage likely did not put food into the hopper after she handled the cage. However, three DAR husbandry caretakers (one on each of the three days) did not identify these two cages without food during routine observations performed in the morning and afternoon between January 13 and 15, contributing to the situation. It is evident that the investigative staff made a mistake by not ensuring that these cages had food, and the DAR husbandry staff failed to identify the issue and fix the cage food hoppers during any of their routine observations.

### Corrective action plan:

(1) The investigator was notified and the lab staff member involved in this incident has been counseled and retrained by the investigator. Axel V. Wolff. M.S., D.V.M. February 15, 2022 Page 2

- (2) The investigator has asked all of his lab staff members to ensure adequate food and water each time after they handle cages containing animals, especially when splitting or weaning animals into a new cage. Documentation of internal counseling/training was provided to the Director of Animal Care and Use Program on February 7<sup>th</sup>.
- (3) If lab members find any cages without adequate food/water levels, they are required to report to the appropriate DAR vivarium manager immediately as well as report it via the DAR Ticketing System (DARTS).
- (4) DAR leadership has performed an in-depth analysis of card key scans for each of the affected building's caretakers to evaluate time spent on tasks such as morning and afternoon health observations. The resulting information was discussed with staff members. There were times during which it was evident that both caretakers did not spend sufficient time per cage to evaluate animal health and verify adequate food/water levels, therefore, both caretakers were asked to slow down, especially in the room where this incident occurred.
- (5) The DAR Program Director/Attending Veterinarian and DAR Assistant Director, Program Development counseled both DAR caretakers involved in this incident. It is rare to involve the Director directly in retraining; however DAR leadership believed that the caretakers might be better understand the seriousness of the issue with the Program Director's participation. Caretakers received counseling regarding proper health observation procedures, with an emphasis on taking enough time per cage to allow identification and resolution of issues. Documentation of this retraining was provided to the Director of Animal Care and Use Program and recorded in DAR's training file.
- (6) Due to the ongoing COVID pandemic, DAR has been understaffed due to personnel absences. This building's caretakers have a heavy cage load. The workload has been compounded by the sudden resignation of a caretaker shortly after this incident occurred. On February 7<sup>th</sup>, two senior/experienced caretakers have been reassigned to this building from other buildings to provide support and relieve the workload. One reassignment is permanent, while the other is only until the vacant position has been permanently filled. Some hourly staff in this building will be asked to help the caretakers with tasks that do not involve animal handling (e.g., cage prep, sweeping/mopping, cleaning, collecting dirty cages). This will allow the caretakers to spend less time in support tasks and more time conducting their routine daily AM/PM health observations.
- (7) The new researcher vivarium in-person training script and new animal user virtual orientation will be revised to the importance of lab staff members visually verifying that every cage they handle has adequate food and water and the animals appear healthy before they leave the animal room. This will also be incorporated into our online training modules.
- (8) A broadcast email will be sent to all investigators and lab personnel reminding them to ensure adequate food and water each time after they handle cages containing animals, especially when splitting or weaning animals into a new cage. They will be instructed to develop a habit of visually checking all cages they have handled before leaving the animal room.

Axel V, Wolff, M.S. D.V.M. February 15, 2022 Page 3

Ensuring animal health and well-being is a critical responsibility for all personnel, including all lab staff members/animal users and animal caretakers at DAR. This will be emphasized at every opportunity.

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 on one mouse, 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 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 yours,

(b) (6)

(On behalf of Dr. P. Srirama Rao)

# Wolff, Axel (NIH/OD) [E]

From: Sent:	OLAW Division of Compliance Oversight (NIH/OD)  Friday, February 18, 2022 7:52 AM		
To: Cc:	OLAW Division of Compliance Oversight (NIH/OD)		
Subject:	RE: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)		
Thank you for this report, (b)(6)	I will send a response soon.		
	i will sella a response soon.		
Axel Wolff			
From:	(b) (6)		
Sent: Tuesday, February 15, 2022 To: Wolff, Axel (NIH/OD) [E] <wo< th=""><th>2 5:53 PM  olffa@od.nih.gov&gt;; OLAW Division of Compliance Oversight (NIH/OD)</th></wo<>	2 5:53 PM  olffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD)		
<olawdco@od.nih.gov></olawdco@od.nih.gov>			
Cc: P. Srirama Rao <psrao@vcu.edu> Subject: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)</psrao@vcu.edu>			
sender and are confident the conter	n outside of the organization. Do not click links or open attachments unless you recognize the nt is safe.		
Dear Dr. Wolff,			
Attached please find the follow-up non compliance 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 1/27. 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 qu me at	estions regarding this matter, please do not hesitate to contact remail to:		
Sincerely,			
	(b) (6)		

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Case #\_\_\_\_

	ual Report of Noncompliance
	B <sub>2</sub> (6) (6)
Date: 1/27/22	Time: 830
Name of Person reporting  Telephone #:  Fax #:  Email:	
Name of Institution: VIRGINIA COMM Assurance number: A3281	ion wealth U
Did incident involve PHS funded activity? Yes Funding component: Not Was funding component contacted (if necessary):	
What happened?  ( mouse died - no feed, 2 c other 7 mice pass condition.	ages no jest 2 died Total.
Species involved: Mouse Personnel involved: Dates and times: Animal deaths:	of Caretaria
Projected plan and schedule for correction/prevention	on (if known):
Gunsel, retrain, sonation.	A gel + others recovered,
Projected submission to OLAW of final report from	Institutional Official:
OFFICE USE ONLY	