



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 24, 2022

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

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 16, 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 October 11, 2022. According to the information provided, OLAW understands that two mice died and four were euthanized due to poor condition as a result of having no food. The mice had been weaned by research staff who stated that food had been supplied. The animal care staff failed to identify the problem during the daily health checks.

The corrective actions consisted of notifying the investigator and staff that cages are to be checked for the presence of food/water and that the animals are healthy following cage manipulation and weaning. One of the caretakers involved has received a written warning, the other caretaker was retrained, and all caretakers have been counseled on the proper performance of health checks. Because this noncompliance constitutes a recurrence, the daily health observation standard operating procedure was revised to include a daily comprehensive cage exam consisting of pulling out the cage to check the animals, food/water, and bedding. All research staff must double check cages for food/water and animal health following each cage handling.

Based on its assessment of this explanation, OLAW understands that measures are underway 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

(b) (6)

A3281-2T



**VCU**

Office of Research and Innovation

October 16, 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, (b) (4)  
Box 980568  
Richmond, VA 23298-0568

(b) (6)  
[IACUC@VCU.EDU](mailto: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 four lethargic mice due to lack of food, which I discussed and reported to you via a telephone call on October 11, 2022.

**Description of Incident:**

During morning observations on September 26, the Division of Animal Resources (DAR) animal care staff reported two cages that each contained one dead mouse and two lethargic mice. The investigator and veterinary staff were notified immediately. The four lethargic mice were subsequently euthanized per the research personnel's request. The cages were examined and water was present in the form of a working hydropac. However, no food was present in the cage or in the hopper, and very little feces was present in the cage. Research staff indicated that the animals had been weaned on September 22 and that they had put food into the cage at that time, although this could not be confirmed. However, both weekday and weekend DAR husbandry caretakers did not identify these two cages without food during routine observations performed in the morning and afternoon between September 23 and 26, contributing to the situation. It is evident that DAR husbandry staff failed to identify the issue and fill the food hoppers during any of their routine observations.

**Corrective action plan:**

- (1) On October 11, a memo including corrective actions and potential sanctions (a temporary suspension of animal room access and possible suspension of the protocol), was sent to the investigator and the research staff who were involved in this incident to ensure that they will check every cage they have handled before leaving the animal room to make sure each cage has adequate food and water and that the animals appear to be healthy. When new cages are set up, the food hopper must be completely filled with food and water should be no less than  $\frac{3}{4}$  full at all times.
- (2) One of the DAR husbandry caretakers involved in this incident has received a Written Counseling Memo, which states that any future performance and/or conduct deficiencies that are in violation of VCU's ethical standards will result in formal disciplinary action. Additionally, this incident may also be taken into consideration when evaluating their annual performance.
- (3) The other DAR husbandry staff member involved in this incident has 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 Operations. Documentation of this retraining will be provided to the Director of the Animal Care and Use Program.
- (4) In order to minimize the possibility of a similar incident occurring in the future, all DAR staff with animal husbandry responsibilities will be reminded of proper procedures and the consequences to the animals if observations are rushed. Documentation and description of this meeting received during the staff meeting will be provided to the Director of Animal Care and Use Program as well as maintained in DAR's training folder.
- (5) Because of the recurrence of this type of incident this year, DAR is revising its daily health observation SOP. Husbandry staff are being transitioned to a once-daily comprehensive health observation procedure, which will begin on October 24 for the animal facility where this incident occurred. This practice will be introduced to the other animal facilities in phases to ensure a smooth transition period for each area. The previous SOP involved a twice-daily check of each cage without handling (i.e., using a penlight to examine the cage from the front only). This will be replaced by a more comprehensive examination of each cage, to be performed once daily. 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 flow), verified that every bottle is functioning properly, and verified that the animals appear as healthy as possible.

Axel V, Wolff, M.S. D.V.M.  
October 16, 2022  
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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]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, October 18, 2022 12:05 PM  
**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 afternoon (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:** Sunday, October 16, 2022 11:18 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)

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 10/11. 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)

Sincerely,

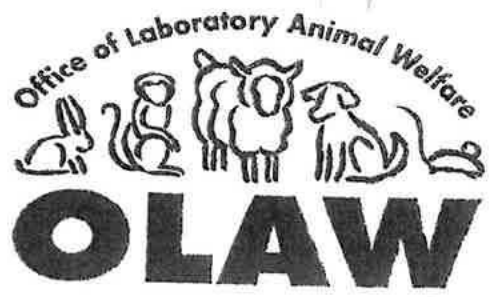
(b) (6)



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(b) (6)



### Initial Report of Noncompliance

By: (b) (6)

Date: 10/11/22

Time: 10:15

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

*2 mice died, 4 rats die to no food  
Weaned, no food, problem not caught by caretakers*

Species involved:  
Personnel involved:  
Dates and times:  
Animal deaths: 6

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

*Write up caretakers HR, retrain, counsel  
Must now open cages to check. Retrain lab staff  
on handling + ensuring food present. Discipline  
as needed.*

Projected submission to OLAW of final report from Institutional Official:

*Receive certification  
from PI*

OFFICE USE ONLY  
Case # \_\_\_\_\_