



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

December 20, 2023

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

P. Srirama Rao, Ph.D.
Vice President for Research and Innovation
Virginia Commonwealth University
800 East Leigh St
Biotech One- (b) (4)
Richmond, VA 23219

Dear Dr. Rao,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Virginia Commonwealth University (VCU) following up on an initial December 18, 2023 notification by telephone.

According to the information provided, this office understands that the VCU Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to conditions the jeopardized the health/well-being of animals resulting in harm/death to animals. The final report states on November 12, 2023, a cage of mice was discovered without food. One animal was found dead, and the remaining mice were reported to have decreased activity. In response, diet gel was provided to the animals, and they appeared to be recovering (per the report). Ultimately, a laboratory staff member decided to euthanize the remaining animals. Investigative results determined the lab member who weaned the mice did not place food in the hopper after handling the cage. It is stated that 2 husbandry caretakers did not identify the cage or fix the food hopper during their routine observations.

In response to the incident, the following corrective actions were implemented (in summary):

- On December 5, 2023, the lab staff member received retraining on double-checking to visually verify that each cage handled has adequate food and water prior to leaving the room for the day.
- DAR husbandry staff members involved in the incident will receive refresher training on proper health observation procedures.
- All DAR staff with husbandry responsibilities were reminded of proper procedures and the consequences to the animals if observations are rushed.
- A broadcast email will be sent to all investigators and lab personnel reminding them to ensure adequate food and water are present each time after they handle cages containing animals, especially when splitting or weaning animals to a new cage.

It is noted the associated research project is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Virginia Commonwealth University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 – Dr. Rao
December 20, 2023
OLAW Case A3281-2V

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.

Tubbs-S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2023.12.20 13:14:07
-05'00'

Jacquelyn Tubbs, DVM, DACLAM

Senior Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

A3281-2V



Office of Research and Innovation

December 20, 2023

Jacquelyn Tubbs, D.V.M.,
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
(301) 402-2081

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. Tubbs:

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 mouse and three mice euthanized due to lack of food, which I discussed and reported to you via a telephone call on December 18, 2023.

Description of Incident:

One cage of mice was found without food during health observations on Sunday, November 12, 2023. One was found dead and the remaining three were reported to have decreased activity, but they began eating dietgel provided by the husbandry staff member and appeared to be recovering. The lab staff member subsequently decided to euthanize the remaining three mice. The investigation revealed that the lab staff member who weaned the animals did not put food into the hopper after handling the cage. However, the two DAR husbandry caretakers did not identify the cage during their routine observations, contributing to the situation. It is evident that the investigative staff made a mistake by not ensuring that this cage had food, and the DAR husbandry staff failed to identify the issue and fix the cage food hopper during any of their routine observations.

Corrective action plan:

- (1) The investigator was notified. On December 5th, the lab staff member received individual retraining on double-checking to visually verify that each cage handled had adequate food and water before leaving the room for the day. Documentation of this training was provided to the Director of the Animal Care and Use Program (ACUP).

Jacquelyn Tubbs D.V.M.
December 20, 2023

- (2) The DAR husbandry staff members involved in this incident will receive 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 ACUP.
- (3) In order to minimize the possibility of a similar incident occurring in the future, all DAR staff with animal husbandry responsibilities were reminded of proper procedures and the consequences to the animals if observations are rushed. Documentation and description of this meeting received during the 11/15/23 staff meeting were provided to the Director of ACUP on December 8 as well as maintained in DAR's training folder.
- (4) 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.

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.

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 adjust 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)

Ware, Teagan (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Wednesday, December 20, 2023 11:11 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Srirama Rao; (b) (6)
Subject: RE: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Hello!

Thank you for the final report. We will send an official response soon.

Kind Regards,

J. Tubbs

From: (b) (6)
Sent: Wednesday, December 20, 2023 11:02 AM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@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. Tubbs,

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 12/18. The written report includes a detailed explanation of the situation and actions taken by VCU IACUC.

In addition, I'd like to provide you with a copy of the delegation of signatory authority memo which was also on file with OLAW Assurance Division.

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)

(b) (6)

A3281-2V



Initial Report of Noncompliance

By: J. Tubbs

Date: 12-18-2023

Time: 12:50pm

Name of Person reporting (b) (6)

Telephone #:

Fax #:

Email: (b) (6)

Name of Institution: Virginia Commonwealth University
Assurance number: D16-00180 (A3281-01)

Did incident involve PHS funded activity? TBD

Funding component:

Was funding component contacted (if necessary): _____

What happened?

A cage with 4 animals, 1 found dead, and the cage had water but no food. Researcher forgot to put food in the cage. Remaining animals were euthanized by the lab.

Species involved: mice

Personnel involved: research staff

Dates and times: late November

Animal deaths: yes

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

Projected submission to OLAW of final report from Institutional Official:
60-90d

OFFICE USE ONLY

Case # _____