



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, 2021

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

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 December 16, 2021 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 December 10, 2021. According to the information provided, OLAW understands that one mouse died due to lack of food because the investigator who had handled the cage failed to fill the hopper. The problem was not identified during the daily health check. Another mouse in the same cage was weak but recovered with supportive care.

The corrective actions consisted of counseling and retraining the laboratory member and animal caretaker responsible. All caretaking staff was reminded to take time to observe cages and animals carefully.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a recurrence of this problem. While OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, we note that ongoing incidents of this type must be met with escalating corrective measures or sanctions for staff to eliminate this serious animal welfare concern. 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

(b) (6)



VCU

Office of Research and Innovation

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

December 16, 2021

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

(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 December 10, 2021.

Description of Incident:

During morning health observations on December 6th, one animal was found dead, with no food in the cage hopper. The cage hopper was also turned backwards in the cage, although this had no impact on the animals' ability to reach food. The other animal was noted to have decreased activity, so wet food and dietgel were placed onto the cage floor. The animal was given supportive care and appears to be recovering well. Veterinary staff were notified. The investigation revealed that the researcher who handled the cage did not put food into the hopper. The lab confirmed that the lab staff handled this cage on December 3rd. However, the DAR weekend husbandry caretaker did not identify this cage during routine observations performed in the morning and afternoon of both weekend days. Therefore, it is evident that the investigative staff made a mistake by not ensuring that the cage had food, and the DAR weekend care taker failed to identify the issue and fix the cage food hopper during any of his routine observations.

Corrective action plan:

- (1) The investigator was notified and the lab staff involved in this incident will be counseled and retrained by the investigator.

Axel V. Wolff, M.S., D.V.M.

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- (2) The DAR weekend husbandry caretaker involved in this incident received individual counseling and retraining 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.
- (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 staff meeting was provided to the Director of Animal Care and Use Program as well as maintained in DAR's training folder.

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)



Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 17, 2021 7:20 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)

Thank you for this report, (b) (6) We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Thursday, December 16, 2021 8:48 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: P. Srirama Rao <psrao@vcu.edu>
Subject: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content 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 12/10 . 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 to: (b) (6)

Sincerely,

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(b) (6)





Initial Report of Noncompliance

By: (b) (6)

Date: 12/10/21

Time: 10:30

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?

1 mouse died due to reversed food trays

Species involved: mouse

Personnel involved:

Dates and times:

Animal deaths: 1

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

Cancel research staff, restrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____