



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 28, 2024

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

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 final report, dated October 10, 2024, of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Commonwealth University. Initial notification was provided by phone on October 1, 2024. According to the information provided, OLAW understands that between July 18 and 19, 2024, multiple cages of deceased mice were found during routine health checks. A total of eight mice were found deceased, and five others were euthanized due to lethargy despite diet supplementation and support being provided. The animals had been subject to oral gavage by students who had practiced the technique without prior issues. The issue likely arose from complications with the oral gavage technique. An investigation concluded that the students require additional formal training on oral gavage technique and closer monitoring of animals following the administration of solutions by oral gavage. The animals involved were part of a PHS-funded research project.

Corrective and preventive actions:

1. All laboratory staff, including students who performed oral gavage on the affected animals, will undergo retraining and be observed by DAR veterinary staff before any future oral gavage procedures.
2. The protocol has been amended to include a monitoring schedule for mice following oral gavage. Laboratory staff will continuously observe each animal for the first 5 minutes post-administration, followed by additional checks at 1 hour and 1-day post-gavage.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

BRENT C. MORSE -S

Digitally signed by BRENT C.

MORSE -S

Date: 2024.10.28 07:33:36 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

(b) (6)



October 10, 2024

Brent Morse, D.V.M., Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
(301) 496-7163

Virginia Commonwealth University

Office of the Vice President for  
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[research.vcu.edu](https://research.vcu.edu)

P. Srirama Rao, Ph.D.  
Vice president for research and  
innovation

VCU Animal Welfare Assurance number D16-00180 (A3281-01)

Dear Dr. Morse:

Virginia Commonwealth University, in accordance with Assurance D16-00180 (A3281-01) and PHS Policy IV.F.3., submits this report of noncompliance involving the death of eight mice and the euthanasia of five others. This incident was discussed and reported to you during a Zoom meeting on October 1, 2024.

**Description of Incident:**

Between July 18 and 19, the Division of Animal Resources (DAR) staff found multiple cages of deceased mice during their routine health checks. A total of eight mice were found deceased, and five others were euthanized due to lethargy despite diet supplementation and support being provided. DAR veterinary staff immediately notified the lab.

The animals had been administered 0.5 mg/kg of letrozole dissolved in a 30% hydroxypropyl- $\beta$ -cyclodextrin vehicle solution via oral gavage. The letrozole solution was prepared the previous day and administered by students who had practiced the oral gavage technique without prior issues. Following the administration of letrozole or the vehicle solution by oral gavage, several animals were found deceased or displaying breathing difficulties. The issue likely arose from complications with the oral gavage technique.

Our investigation concluded that the students require additional formal training on oral gavage technique and closer monitoring of animals following the administration of solutions by oral gavage.

**Corrective action plan:**

An adverse event report was submitted by the investigator detailing the corrective actions outlined below. The IACUC reviewed and approved this report on August 14, 2024.



1. All laboratory staff, including students who performed oral gavage on the affected animals, will undergo retraining and be observed by DAR veterinary staff. It is the lab's responsibility to schedule the retraining and request veterinary observation for each staff member before any future oral gavage procedures. To prevent future incidents, lab members must complete appropriate training and request veterinary observation to assess their proficiency. Documentation of this training and observation will be required and verified during post-approval compliance monitoring (PACM) inspections.
2. The protocol has been amended to include a monitoring schedule for mice following oral gavage. Laboratory staff will continuously observe each animal for the first 5 minutes post-administration, followed by additional checks at 1 hour and 1 day post-gavage.

Although the animals involved were part of a PHS-funded research project, a review of the direct costs associated with the procurement, care, and use of these animals determined that the financial impact of this noncompliance is insignificant. Therefore, no adjustment to the grant is necessary.

We deeply regret this incident and have taken specific corrective actions to enhance our program and prevent future occurrences. These actions were reviewed and approved by the IACUC during their full committee meeting on August 14, 2024.

We appreciate your consideration of VCU's efforts to minimize future incidents. VCU remains committed to animal welfare and acknowledges its ethical responsibilities in ensuring the well-being of research animals and complying with the PHS Policy on the Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

P. Srirama Rao, Ph.D.

Vice President for Research and Innovation

**Ware, Teagan (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, October 11, 2024 9:58 AM  
**To:** (b) (6)  
**Cc:** Srirama Rao; (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Good morning,

Thank you for providing this final report for OLAW case **A3281-2Z**. We will send an official response soon.

Best,  
Teagan

Teagan Ware, MS, PMP  
Animal Welfare Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [teagan.ware@nih.gov](mailto:teagan.ware@nih.gov)

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**From:** (b) (6)  
**Sent:** Friday, October 11, 2024 9:45 AM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.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. Morse,

Please find attached the follow-up noncompliance letter, signed by VCU's Institutional Official, Dr. Rao, who is copied on this email. On October 1st, I gave you preliminary information about this situation during our Zoom meeting. The attached report now provides a thorough explanation of the issue and details the actions taken by the VCU IACUC.

We greatly appreciate your attention to this matter. VCU remains fully committed to adhering to the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Guide, while upholding our unwavering commitment to animal welfare.

Should you have any questions or need further clarification, please do not hesitate to



contact me at (b) (6) or via email at (b) (6)

Best regards,

Sincerely,

(b) (6)



A3281-2Z

## Initial Report of Noncompliance

By: BCM

Date: 10/1/2024

Time: 10:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Virginia Commonwealth Univ. \_\_\_\_\_

Assurance number: A3281 \_\_\_\_\_

Did incident involve PHS funded activity? yes \_\_\_\_\_

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened: 8 mice found dead or euthanized. Student administering drug via oral gavage may have not demonstrated proficiency. Student no longer with lab.

Species involved: mus

Personnel involved: student

Dates and times: 7/18/2024

Animal deaths: found dead or euthanized

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

Requiring demonstration of proficiency for this lab being considered.

Projected submission to OLAW of final report from Institutional Official:

< 60 days.

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Case # \_\_\_\_\_