



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

July 20, 2020

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

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 July 9, 2020 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 July 8, 2020 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: the deaths of 6 mice and euthanasia of one mouse. The final report states on June 26, 2020 a Division of Animal Resources (DAR) caretaker discovered a breeding cage with a dead female mouse, a male and seven pups during afternoon health observations. The dead mouse was removed by the caretaker. However, food supplement was not provided to the animals nor was on-site veterinary staff notified to evaluate the cage and contact research personnel. On June 29, 2020 a different caretaker found six dead pups and an additional pup was moribund and euthanized by vet staff.

An investigation revealed that the DAR caretaker working on June 26th failed to provide food supplements on the cage floor and notify the on-site veterinary staff. The corrective action plan included the following:

- Individual counseling and retraining regarding proper procedures to place food supplements or gel into cages as well as report to veterinary staff for examination has been provided to the original DAR caretaker. This individual will have to complete a Performance Improvement Plan. Also, this individual will need to retake the entire Fundamentals for Animal Caretakers training.
- At the next DAR staff meeting, all staff with husbandry duties will be reminded to increase awareness regarding proper procedures to place food supplements or gel into cages as well as report to veterinary staff for examination.

It is understood that the IACUC will be advised of the above corrective actions at their next full committee meeting. It is noted that the final report did not include the funding source involving the incident. In the future, please include the source of funding and provide grant numbers for all PHS, NSF or NASA supported work. It is understood that this matter was not research-related, but again, please provide this information in the future because it is pertinent to this Office.

Page 2 – Dr. Rao
July 10, 2020
OLAW Case A3281-2N

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

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



VCU

Office of Research and Innovation

July 9, 2020

Axel V. Wolff, M.S., D.V.M.,
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 6700B Rockledge Drive
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 Animal Care and Use Program
 Virginia Commonwealth University
 BioTechnology Research Park
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 (804) 828-6587, Fax: (804) 827-1448
IACUC@VCU.EDU

Amy Chuang, M.S.
 Director of Animal Care and Use
 Program (ACUP)

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 six mice and one euthanized. I have reported to you on July 8, 2020 via a telephone call.

Description of Incident:

On Friday, June 26, a Division of Animal Resources (DAR) caretaker found a breeding cage containing a dead female mouse, a male and seven pups (DOB 6/14/2020) during afternoon health observations. The caretaker removed the carcass but did not place food supplements on the cage floor or notify the on-site veterinary staff to evaluate the cage and contact research personnel. On Monday, June 29, a different DAR caretaker found six of the seven pups dead; the last pup was moribund and was euthanized per veterinary staff. The investigation revealed that the original DAR caretaker (working on 6/26) failed to take appropriate actions to provide food supplements on the cage floor and notify the on-site veterinary staff.

Corrective action plan:

- (1) The DAR caretaker involved in this incident received individual counseling and retraining regarding proper procedures to place food supplements or gel into cages as well as report to veterinary staff for examination. The caretaker has received a written counselling and will have to complete a Performance Improvement Plan. This plan will including the following: He will have a 90-day timeline to complete online training related to building trust, holding one's self accountable, succeeding in the job, how to be promotable, and overcoming overwhelm. In addition, he will need to retake the entire Fundamentals for Animal Caretakers training. This training consists of five PowerPoint modules presented lecture-style by a senior DAR leadership member, written reviews for

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

July 9, 2020

Page 2

each module to test knowledge absorption and understanding, and practical (in-room or in-person) reviews for four modules. The Fundamentals program covers a wide range of topics, starting from a new caretaker's first day in an animal room and including topics such as how to respond to sick/injured animals, emergency health issue response (e.g., added wetted food or gel to cage floor and contact vet staff ASAP), and various federal regulatory bodies that impact our field. The caretaker must complete the Fundamentals program by August 31, 2020. Documentation of this retraining will be provided to the Director of Animal Care and Use Program and recorded in DAR's training file.

- (2) In order to minimize the possibility of a similar incident occurring in the future, at the next DAR staff meeting all DAR staff with animal husbandry responsibilities will be reminded to increase awareness regarding proper procedures to place food supplements or gel into cages as well as report to veterinary staff for examination. Documentation and description of information delivered 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.

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,

DocuSigned by:
[Redacted Signature] (b) (6)
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Amy Chuang, M.S., RQAP-GLP, CPIA
Director, Animal Care and Use Program
Office of Research and Innovation



VCU

Office of Research and Innovation

Office of Research and Innovation
Virginia Commonwealth University

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Richmond, Virginia 23298-0568
804 827-2262 Fax: 804 828-2051
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Delegation of Signatory Authority Memorandum

To: Kuei-Lan Chuang, Director, Animal Care and Use Program
From: P. Srirama Rao, Vice President for Research and Innovation
Date: July 1, 2020
Subject: Delegation of Signatory Authority

By means of this Memorandum, I, P. Srirama Rao, Vice President for Research and Innovation hereby delegate the authority to execute (1) Memoranda of Understanding for IACUC oversight; (2) AAALAC Annual Report (electronic submission); and (3) OLAW noncompliance report letters (with cc to me) to Kuei-Lan Chuang, Director, Animal Care and Use Program.

This delegation of signatory authority is in compliance with VCU Board Policy, Delegation of Signatory Authority (amended 2019), and relevant laws.

This delegation shall be effective until the earlier of June 30, 2021 or the date that Kuei-Lan Chuang no longer holds the title of Director, Animal Care and Use Program.

DocuSigned by:
[Redacted] (b) (6) 6/11/2020
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P. Srirama Rao Date
Vice President for Research and Innovation

I accept this delegation and the responsibilities that come herewith.

DocuSigned by:
[Redacted] (b) (6) 6/16/2020
3487C182480543F...
Kuei-Lan Chuang Date
Director, Animal Care and Use Program

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 10, 2020 7:23 AM
To: Kuei-Lan Chuang
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Thank you for this report, Amy. We will send a response soon.
Axel Wolff

From: Kuei-Lan Chuang <kchuang@vcu.edu>
Sent: Thursday, July 9, 2020 5:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: P. Srirama Rao <psrao@vcu.edu>
Subject: Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

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 some preliminary information to you by phone on July 8. The written report includes a detailed explanation of the situation and actions taken by VCU IACUC. In addition, I attach a copy of the delegation of signatory authority to allow me to sign the OLAW noncompliance report letters on behalf of Dr. Rao.

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 [REDACTED] ^{(b) (6)} or email to: kchuang@vcu.edu.

Sincerely,

Amy Chuang

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Amy

Amy Chuang, M.S., RQAP-GLP, CPIA
Director for the Animal Care and Use Program (ACUP)
Office of Research and Innovation
Virginia Commonwealth University
Box 980568
Richmond, VA 23298

(b) (6)

kchuang@vcu.edu

Animal Research website: <https://research.vcu.edu/secure/acup/index.htm>

Animal Care and Use Program Blog: <http://wp.vcu.edu/acup/>

Note: IACUC office is physically closed with staff working remotely. All IACUC protocol submissions, email, phone lines, and online chat are being responded to as usual.



Initial Report of Noncompliance

By: [REDACTED] (b) (6)

Date: 7/8/20

Time: 10:00

Name of Person reporting: Amy Cheema

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: VIRGINIA COMMONWEALTH U

Assurance number: A3281

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

1 female dead in breeding cage, pups not weaned, caretaker told to put food on floor but didn't, 6 pups died

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths: 1 adult, 6 pups

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

Counsel caretaker, evaluation, performance improvement plan

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____