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

May 28, 2019

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163

Facsimile: (301) 402-7065

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

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 final report, dated May 20, 2019, 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 May 6th. According to the information provided, OLAW understands that on Monday morning, April 29th three mice were found dead in the cage. A lack of access to drinking water was the apparent cause. Although there was water in the Hydropac water pouch, the water level was too low for the animals to access. The weekend caretaker failed to detect the low water issue. It was stated that the related animal activity was not PHS funded.

Corrective actions included the counseling and retraining of the responsible weekend animal caretaker. DAR staff with animal husbandry responsibilities will be apprised of this incident and retrained to increase awareness regarding food and water in each cage. A water bottle will be placed in each cage for this investigator to supplement the Hydropac pouches. DAR management will conduct random health check quality control for this room. DAR management is considering workload changes to increase effective monitoring of certain buildings on the weekends.

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. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely, (b) (6)

Brent C. Morse, DVM

Director

Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

(b) (6



Office of Research and Innovation

May 20, 2019

Brent Morse, D.V.M., 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

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., provides this report of noncompliance regarding the death of 3 mice due to lack of water. This incident was reported to you on May 7, 2019 via a telephone call by Ms. Amy Chuang, Director of Animal Care and Use Program, Office of Research and Innovation.

Description of Incident:

During morning health observations on Monday, April 29th, three male mice in a single cage were found dead. After the veterinarian examined the animals & the cage with the investigator's staff, it appeared that the Hydropac water pouch was low enough that animals would not have been able to obtain water. The Lixit appeared to have been chewed and damaged, although the valve mechanism appeared to be fully functional when it was tested with a fresh Hydropac pouch. The veterinarian performed a gross necropsy and determined that animals likely died no more than 12 hours earlier, as there was a general lack of internal organ decomposition. The animals did appear to be mildly dehydrated. The DAR animal caretaker who performed health observations was not the same as the individual involve in the prior incident reported in March 2019. However, the weekend animal caretaker did not detect the water level low issue with this cage, resulting in the deaths of the animals.

Corrective action plan:

(1) The DAR animal caretaker involved in this incident received individual counseling and retraining on proper health observation procedure, which emphasized the importance of verifying appropriate food and water levels and overall animal health. Documentation of this counseling and retraining will be provided to the Director of Animal Care and Use Program and also recorded in DAR's training file.

Office of Research and Innovation Virginia Commonwealth University

BioTech One, 3rd Floor, Suite 3000 800 East Leigh Street P.O. Box 980568 — Richmond, Virginia 23298-0568 804 827-2262 • Fax: 804 828-2051

psrac@vcu.edu

P. Srirama Rao, PhD Vice President for Research and Innovation Professor of Microbiology and Immunology, School of Medicine

- (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 apprised of this incident and retrained in order to increase awareness regarding verification of food and water in each cage. Documentation and description of this meeting received during the staff meeting will be recorded and maintained in DAR's training folder.
- (3) For this particular investigator, DAR began to place a water bottle into each cage to supplement the Hydropac pouches.
- (4) DAR management will randomly conduct a health check quality control for this room to determine animal caretakers are operating with a high level of attention to details, especially verifying food and water levels based on SOP titled "Health Check Quality Control Verification".
- (5) A thorough investigation of this incident, viewed in combination with prior similar reported event, determined that staffing levels allocated to weekend shift work to certain buildings have been inadequate to effectively monitor animal husbandry and health as animal numbers have increased. As a result, DAR management is considering workload changes to increase effective monitoring.

The animals and protocol involved are not PHS funded.

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,



P. Srirama Rao, PhD Vice President for Research and Innovation Professor of Microbiology and Immunology, School of Medicine

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Tuesday, May 21, 2019 2:29 PM

To:

Kuei-Lan Chuang; OLAW Division of Compliance Oversight (NIH/OD)

Cc:

Srirama Rao: (b) (6)

Subject:

RE: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Thank you for providing this report Ms. Chuang. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Kuei-Lan Chuang [mailto:kchuang@vcu.edu]

Sent: Monday, May 20, 2019 2:35 PM

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: Follow-up letter (VCU Assurance# D16-00180/A3281-01)

Dear Dr. Morse,

Attached please find the follow-up letter signed by Dr. Rao, VCU Institutional Official. The incident was reported to you by phone on May 7. The written report includes a detailed explanation of the incident and actions taken by VCU IACUC.

We have reviewed this incident thoroughly and deployed specific corrective actions designed to enhance our animal program and to prevent future occurrences. 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 to: kchuang@vcu.edu.

Best Regards,

Amy Chuang



Initial Report of Noncompliance

Time: 1,15 Name of Person reporting: Telephone #: (b) (6) Fax #: Email: Name of Institution: Assurance number: Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary): What happened? 4 mice dead in one cage was so low animals could Species involved: Mice Personnel involved: Dates and times: 4/29/19 Animal deaths: Projected plan and schedule for correction/prevention (if known): Retrain & coursel

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #_