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

June 21, 2024

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

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 June 13, 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 June 11th. According to the information provided, OLAW understands that a cage containing four mice was found with a Hydropac pouch improperly placed, not fully attached to the lixit. As a result, the mice could not access water, leading to the death of three mice. The fourth mouse was in critical condition and was euthanized by the veterinary staff. Upon examination, it was also determined that the lixit's actuator was chewed, which made it more difficult for water to flow even when the Hydropac was properly seated.

The lab staff member who set up the cage on May 14 failed to verify the proper functioning of the Hydropac watering system before returning the animals to the rack. In addition, the primary DAR husbandry staff member did not recognize the declining health of the animals.

Corrective action plan:

1. The lab member involved in this incident received retraining on proper cage setup and verification procedures.
2. The DAR staff member has been re-trained by vivarium management, with documentation maintained by HR.
3. To prevent similar incidents in the future, all DAR staff with animal husbandry responsibilities will be instructed to verify that each Hydropac cage has a visible lixit protruding into the cage from the water hopper during comprehensive daily health observations.

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.

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: 2024.06.21 13:34:40 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

(b) (6)

A3281-2x

VCU

Virginia Commonwealth University

Office of the Vice President for Research and Innovation

BioTech One, Suite (b) (4)
800 East Leigh Street
Box 980568
Richmond, Virginia 23298
(b) (6)

research.vcu.edu

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

June 13, 2024

Brent Morse, D.V.M., Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
(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 three mice and one euthanized. This incident was reported to Dr. Brent Morse on June 11, 2024, via a telephone call.

Description of Incident:

A cage containing four mice was found with a Hydropac pouch improperly placed, not fully attached to the lixit. As a result, the mice could not access water, leading to the death of three mice. The fourth mouse was in critical condition and was euthanized by the veterinary staff. Upon examination, it was determined that the Hydropac was not correctly seated on the lixit, preventing water flow. Additionally, the lixit's actuator was chewed, which made it more difficult for water to flow even when the Hydropac was properly seated. Both the investigator and the veterinary staff were promptly informed of the situation.

The investigation concluded that the Hydropac water pouch was not pushed fully onto the lixit, which caused the mice to be deprived of water. The lab staff member who set up the cage on May 14 failed to verify the proper functioning of the Hydropac watering system before returning the animals to the rack. In addition, the primary DAR husbandry staff member did not recognize the declining health of the animals.

Corrective action plan:

1. The lab member involved in this incident received retraining on proper cage setup and verification procedures on May 29, 2024. Documentation of this retraining has been submitted to the Director of the Animal Care and Use Program.

2. The DAR staff member has been retrained by vivarium management, with documentation maintained by HR.

3. To prevent similar incidents in the future, all DAR staff with animal husbandry responsibilities will be instructed to verify that each Hydropac cage has a visible lixit protruding into the cage from the water hopper during comprehensive daily health observations. Documentation of this training will be provided to the Director of Animal Care and Use Program and will be maintained in DAR's training folder.

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 sincerely regret this incident and have implemented specific corrective actions to strengthen our program and prevent similar occurrences. The IACUC will be briefed on these corrective actions at their next full committee meeting.

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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 14, 2024 1:37 PM
To: (b) (6)
Cc: Srirama Rao; (b) (6) OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]
Subject: RE: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Good afternoon,

Thank you for providing this final report for OLAW case **A3281-2X**. 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

From: (b) (6)
Sent: Friday, June 14, 2024 1:15 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: [EXTERNAL] Follow-up noncompliance letter (VCU Assurance# D16-00180/A3281-01)

Dear Dr. Morse,

I have attached the follow-up noncompliance letter, signed by VCU's Institutional Official, Dr. Rao (cc'd on this email). On June 11, I provided you with preliminary information regarding this matter via phone. The attached written report offers a comprehensive explanation of the situation and outlines the actions undertaken by VCU IACUC.

We appreciate your attention to this matter. VCU is committed to fulfilling its obligations in compliance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Guide, while maintaining a steadfast commitment to animal welfare.

If you have any questions regarding this issue, please feel free to contact me at (b) (6) (b) (6) or via email at (b) (6)

Sincerely,

(b) (6)

Ware, Teagan (NIH/OD) [E]

From: Ware, Teagan (NIH/OD) [E]
Sent: Thursday, June 13, 2024 11:30 AM
To: Ware, Teagan (NIH/OD) [E]
Subject: FW: [EXTERNAL] phone call follow up

From: (b) (6)
Sent: Thursday, June 13, 2024 11:11 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Re: [EXTERNAL] phone call follow up

Thank you, we are working on our corrective actions and will send a letter to you.

On Thu, Jun 13, 2024 at 10:01 AM Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov> wrote:

Hello (b) (6)

Yes, the issue with the lixit resulting in euthanized mice is reportable. I'll open a case file. Thank you.

Brent C. Morse, DVM, DACLAM

Director, Division of Compliance Oversight

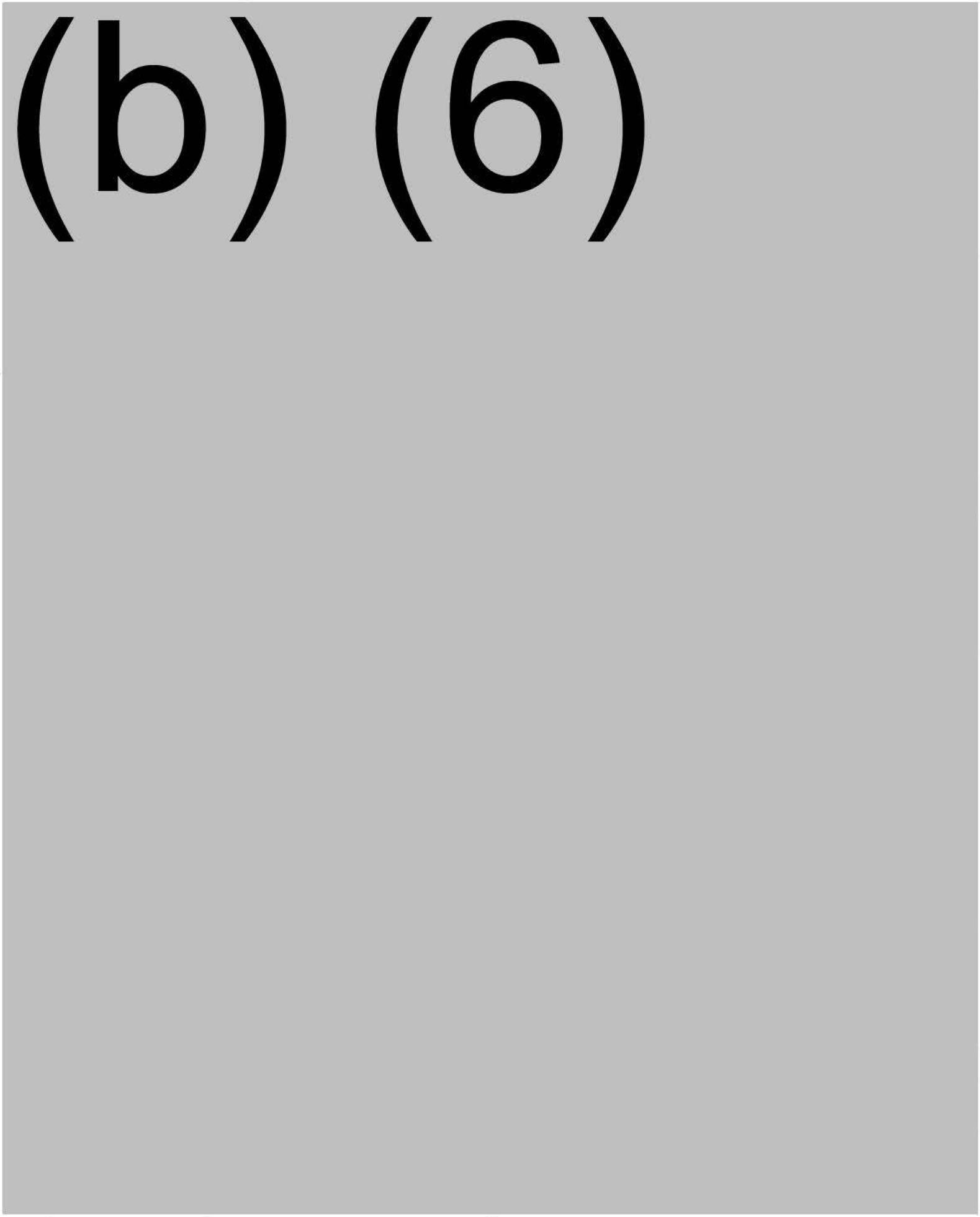
Office of Laboratory Animal Welfare

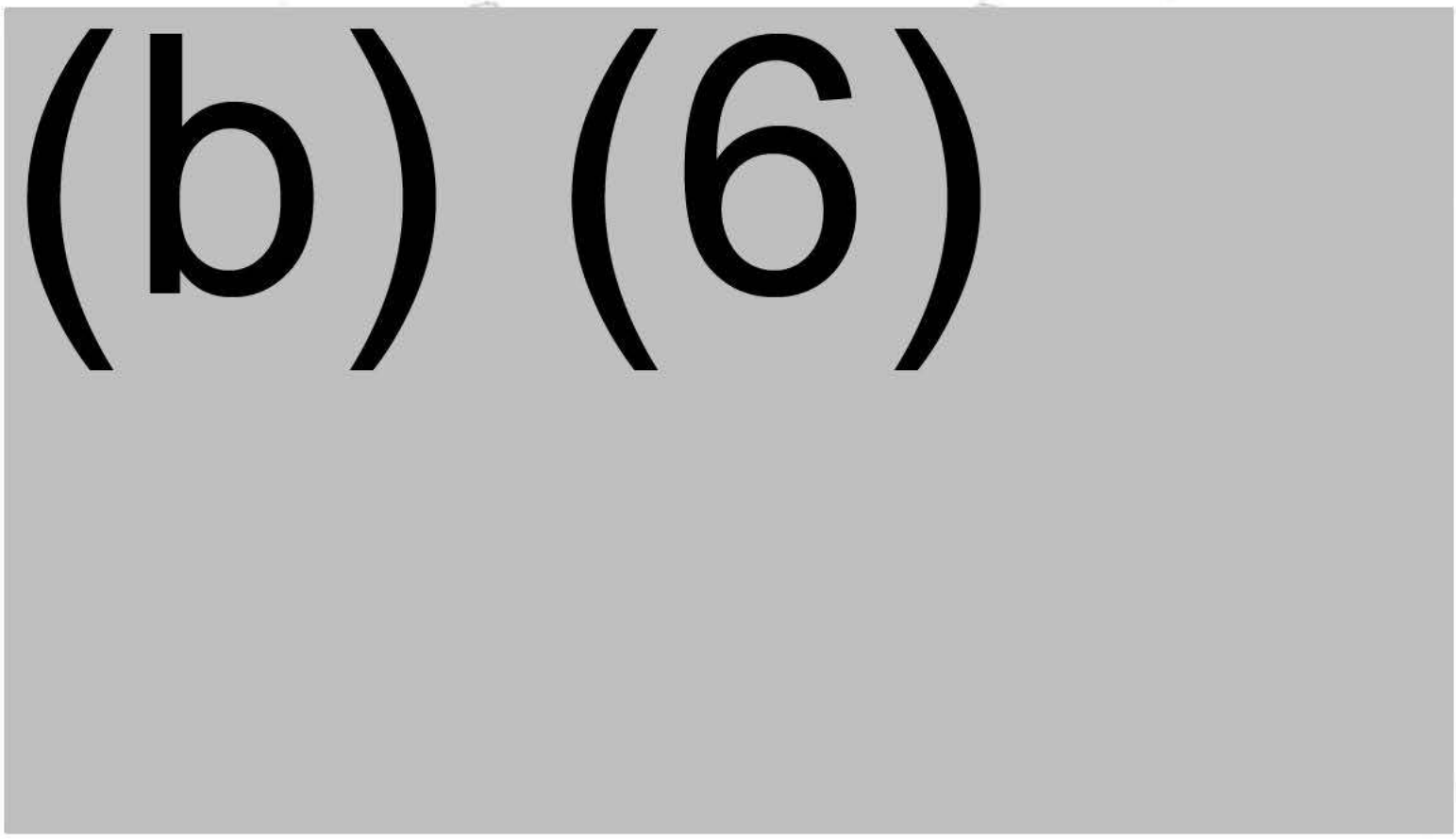
National Institutes of Health

From: (b) (6)
Sent: Wednesday, June 12, 2024 5:16 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] phone call follow up

Hi Brent,

I left you a voice message yesterday and am following up to see if you believe the situation is reportable. Please let me know. Thank you!


(b) (6)


(b) (6)

Office of Laboratory Animal Welfare

OLAW

A3281-2X

Initial Report of Noncompliance

By: BCM

Date: **6/11/2024** Time: 11:07 voicemail

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? __?____
Funding component: _____
Was funding component contacted (if necessary): _____

What happened: Researcher improperly placed hydro pac. No water to lixit valve. Not noticed by care staff

Species involved: Mus
Personnel involved: Researcher, caretaker
Dates and times: ?
Animal deaths: three mice euthanized

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

Training lab member and caretaker

Projected submission to OLAW of final report from Institutional Official:

< 60 days.

OFFICE USE ONLY
Case #_____