



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

August 4, 2022

Re: Animal Welfare Assurance
#A3245-01 (OLAW Case 4N]

Dr. Melur Ramasubramanian
Vice President for Research
University of Virginia
P.O. Box 400301
Charlottesville, VA 22904

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 1, 2022 Animal Welfare Compliance Report describing an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia following up on an initial May 3, 2022 notification by email.

According to the information provided, this Office understands that the University of Virginia Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure to adhere to the IACUC-approved protocol resulting in conditions that jeopardized the health/well-being of animals and resulted in harm or death to animals. The final report states 4 moribund or dead mice were seen on the ground near a parking garage on university grounds. A research building with a vivarium is near the garage and it appeared animals had been inappropriately released outdoors. The Office of Animal Welfare was unable to locate any animals in the specific area.

In response, the Senior Associate Vice President for Research met with the Principal Investigator (PI) and discussed the recent findings. It was made known to the PI that husbandry staff could perform euthanasia of animals if requested, and the animal handler is not required to perform the task. The animal handler that released the animals was identified. The individual stated they were emotionally unable to euthanize additional animals, and subsequently took the animals outdoors and released them. The animals designated for euthanasia were a combination of transgenic breeders and adults. It is stated none of the animals had been on a study, injected, or treated with any substances.

The IACUC voted to immediately revoke the animal handler's privileges, remove the individual from all animal use protocols and suspend their access to the vivarium. The animal handler admitted the release of animals was wrong and expressed remorse. The individual also agreed to resign from their position at the university. The IACUC notified the Institutional Biosafety Committee (IBC) of the intentional release of transgenic mice. In turn the IBC reported the matter to NIH-Office of Science and Policy. Per the report, the committee has integrated additional resources regarding compassion fatigue and reporting concerns to the training program.

It is noted this research is supported by PHS funding. Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance.

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

Page 2 – Dr. Ramasubramanian
August 4, 2022
OLAW Case A3245-4N

Sincerely,

**Jacquelyn T.
Tubbs -S**

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.08.04 08:01:25
-04'00'

**Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare**

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, August 4, 2022 9:26 AM
To: acuc@virginia.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); acuc@virginia.edu;
(b) (6)
Subject: OLAW Case A3245-4N
Attachments: A3245-4N.pdf

Good morning Dr. Ramassubramanian,

Attached please find Dr. Tubbs' final response to OLAW Case A3245-4N. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora


Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

University of Virginia
Animal Welfare Compliance Report
PHS Assurance # A3245-01

The Institutional Animal Care and Use Committee identified the following compliance issue while performing an assessment in the vivaria. A preliminary email notification was sent to the OLAW Division of Compliance Oversight by [REDACTED] ^{(b) (6)} Dr. Axel Wolff acknowledged receipt. It was understood that a full report would be submitted following an IACUC investigation. This document is a summary of the incident, actions taken, and final resolution.

UVA Compliance Case #: 2022-D

Nature of Incident(s):	Failure to adhere to approved protocol resulting in conditions that jeopardized the health and well-being of animals resulting in actual harm or death to animals (mice).
Summary of Incident:	The Attending Veterinarian (AV) reported to the Office of Animal Welfare (OAW) that while walking to work, two separate members of his staff reported seeing approximately four moribund or dead black mice on the ground near a parking garage on university grounds. This parking garage is in close proximity to a research building with a vivarium. The animals appeared to have been taken from a vivarium and inappropriately released outdoors.
Action taken by IACUC:	The OAW immediately went to the area and was unable to locate any animals. Based on preliminary findings and discussions, the Senior Associate Vice President for Research met with the PI and described the recent findings and indicated that if requested the husbandry staff would euthanize identified animals in the colony and that her animal handler would not need to euthanize animals. The specific animal handler that released the animals was identified. While in the vivaria euthanizing mice, the animal handler described having a “mental breakdown” and was emotionally unable to euthanize any additional animals. A small number of animals were taken outdoors and released. The PI confirmed that the animals were slated for euthanasia and were a combination of 45 transgenic breeders or adults. None of the animals had been on study, injected, or treated with any substances. The IACUC convened a special meeting to discuss the serious animal welfare incident. The IACUC voted unanimously to immediately revoke the animal handler privileges of this animal handler and the animal handler was removed from all animal use protocols and their access to the vivarium was suspended. The IACUC notified the PI of their decision.

Action taken by PI:	After meeting with the Senior Associate VP for Research, the PI spoke to the animal handler about the recent findings. The animal handler told the PI that she released the animals. The PI immediately responded to the OAW and provided the details gathered from the animal handler. The PI was in the process of reducing the colony due while preparing to relocate to a different university, and the animal handler had been responsible for euthanizing mice. The PI indicated that the animal handler loves animals and felt distress while euthanizing animals and it was not done because of negligence or lack of animal care. The animal handler acknowledged that releasing the animals was wrong and was very remorseful. After the IACUC notified the PI of their decision to suspend the animal handler the PI communicated to the IACUC that the animal handler agreed to resign from their position at the University.
Action taken by IACUC:	The IACUC decided no further action was deemed necessary by the PI. Due to the deliberate release of transgenic animals, the incident was conveyed to the Institutional Biosafety Committee (IBC). The IBC reported the incident to the NIH-Office of Science and Policy. The IACUC discussed the impacts of euthanizing animals during the next Program Review Meeting. The committee integrated additional resources regarding compassion fatigue and reporting concerns into the training program.
Decision/Resolution:	The IACUC considered the incident resolved.
Federal Funding:	1P01 HL120840
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	 (b) (6)
	Date: August 1, 2022

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 1, 2022 11:15 AM
To: [REDACTED] (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report

Good morning [REDACTED] (b) (6)

Thank you for sending us these reports and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: [REDACTED] (b) (6)
Sent: Monday, August 1, 2022 10:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: [EXTERNAL] OLAW Report

Dr. Axel Wolff,
Director of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health RKL 1,
Suite 360, MSC 7982
6705 Rockledge Dr., Bethesda, MD

Dr. Wolff:

I attach two compliance reports from our IACUC. These are 2022-C and 2022-D.

Preliminary reports were submitted.

Appropriate corrective action has been taken and the IACUC has determined that these matters are now resolved to their satisfaction.

[REDACTED] (b) (6)



Wolff, Axel (NIH/OD) [E]

A3245-4N

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 4, 2022 7:31 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01). Case 2022-D

Thank you for this report, (b) (6). We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, May 3, 2022 5:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] preliminary notification - UVA (Assurance A3245-01). Case 2022-D

Dear OLAW Division of Compliance Oversight,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified a significant deficiency related to genetically modified mice. The UVA tracking number is 2022-D.

The issue is currently under investigation and review by the IACUC. We are working towards resolution and will send a separate compliance report once resolved. It appears that an animal handler released several transgenic mice into the environment instead of performing euthanasia on the animals.

Should you have any questions or concerns prior to receiving our final report, please do not hesitate to contact me.

Sincerely,

(b) (6)