



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

May 12, 2023

Re: Animal Welfare Assurance
#A3245-01 [OLAW Case 4W]

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

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 8, 2023 letter reporting 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 report on March 8, 2023. According to the information provided, OLAW understands that mice were housed in a laboratory that had not been approved as a satellite facility. One of the mice had been directed to be euthanized by the veterinarian, but this was not done.

The immediate action taken upon discovery consisted of euthanizing the mouse. The corrective actions consisted of notifying the Principal Investigator about the deficiencies, prohibiting transfer of animals to another protocol, and prohibiting transport of live animals outside of the vivarium for 90 days. The Institutional Animal Care and Use Committee (IACUC) required the PI to conduct all animal activities within the vivarium and if activities are to be conducted elsewhere, the protocol must be amended. The PI provided a copy of the protocol and relevant policies to the laboratory staff, enhanced communication with the vivarium staff, agreed to the imposed sanctions, and posted signage indicating where animals are to be taken. The PI was counseled on maintaining compliance in the laboratory.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

**University of Virginia
Animal Care and Use Compliance Report
PHS Assurance # A3245-01**

The Institutional Animal Care and Use Committee (IACUC) discovered the following compliance issue and found that it was associated with NIH funds. A preliminary email notification was sent to the OLAW Division of Compliance Oversight by the Director of the Office of Animal Welfare. Devora McCoy, Program Analyst, acknowledged receipt. It was understood that a full report would be submitted following IACUC review. This document is a summary of the incident, actions taken, and final resolution.

UVA Case #: 2023-A
OLAW Case #: A3245- 4W

Nature of Incident(s):	Conducting animal-related activity without appropriate IACUC review and approval; failure to adhere to humane endpoints (mice)
Summary of Incidents:	<p>Two issues were noted at the same time.</p> <p>The husbandry staff reported to the Office of Animal Welfare (OAW) that they suspected six cages of mice had been removed from the vivarium and were being kept in the PI's laboratory space. OAW inspected the laboratory and found some of the missing cages in the laboratory. The PI said that the cages were transported after hours back/forth to the vivarium. Additional evidence indicated that the six cages were maintained in the laboratory space beyond the allowable 24hr period; the protocol did not have approval for temporary housing.</p> <p>One animal, while housed in the vivarium, had been evaluated by the veterinary staff and euthanasia was strongly recommended. The PI confirmed that the animal would be euthanized on the day of discovery. The animal was subsequently found by OAW among the animals being housed in the laboratory. The OAW required that the animal be immediately euthanized.</p>
Action taken by IACUC:	<p>The IACUC discussed these two incidents at a convened meeting.</p> <p>The IACUC determined that the issues were significant deviations.</p> <p>The IACUC sent a letter to the PI notifying them of the deficiencies, immediate sanctions, and required attendance at the next IACUC meeting. The PI's department chair was copied on the correspondence. Immediate restrictions were imposed and continued for 90 days: prohibited from transferring animals to any other protocol, and prohibited from transporting live animals outside of the vivarium (to another vivarium or laboratory).</p> <p>The PI attended the next IACUC meeting as required. Following the meeting, the IACUC sent a letter to the PI (department chair copied). The letter: required the submission of a written corrective action plan; notified the PI of an additional sanction; and, provided the policy on</p>

	sanctions for noncompliance. The letter reminded the PI that continued noncompliance could result in more severe actions including suspension of animal use protocols. The IACUC removed the laboratory locations listed in the protocol(s) further requiring that all animal work occur within the vivarium. At the conclusion of the 90-day period, if the PI wants to take live animals outside of the vivarium, then the PI must submit a major modification to the protocol describing each location, procedure to be performed in the location, and compelling justification for use.
Action taken by PI:	The PI provided a written corrective action plan that included the following actions: forwarded the animal use protocol and associated policies to animal handlers; met with the vivarium supervisor and veterinary technician in the vivarium to discuss issues related to animal care and to enhance communication; acknowledged adherence to sanctions; and provided an example of a sign that would be used and posted in the laboratory as a reminder if approved to take animals to the laboratory in the future. The department chair attended the IACUC meeting with the PI. The chair communicated separately with the IACUC and indicated that the chair and PI met on several occasions to discuss the severity of the incident and importance of compliance.
Action taken by IACUC:	The IACUC felt that no further action was deemed necessary beyond the 90-day restrictions. The full IACUC will review the modification for use of laboratory space if submitted to determine whether the location(s) will be approved.
Decision/Resolution:	The IACUC accepted the corrective actions as submitted by the PI and considered the incident resolved following the 90-day period.
Federal Funding:	R01 DK116768/DK/NIDDK
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	(b) (6) Date: May 8, 2023

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 8, 2023 1:07 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report from UVA IACUC

Good afternoon (b) (6)

Thank you for sending us this final report for case A3245-4W and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA (*pronunciation*)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Monday, May 8, 2023 10:10 AM
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] Compliance Report from UVA IACUC

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 a compliance report from our IACUC. This is UVA 2023-A.

A preliminary report was submitted and was assigned OLAW case number **A3245-4W**

Appropriate corrective action has been taken and the IACUC has determined that this matter is now resolved to their satisfaction.

(b) (6)

A3245-4W

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 9, 2023 6:54 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01); 2023-A

Good morning (b) (6)

Thank you for sending us this preliminary report and we look forward to receiving the final report once completed. This report has been assigned OLAW case number **A3245-4W**, so please reference this number when sending the final report.

Thanks,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Wednesday, March 8, 2023 4:26 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); 2023-A

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 mice. The UVA tracking number is 2023-A.

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 a researcher may have failed to adhere to the IACUC-approved protocol and failed to provide adequate veterinary care resulting in a condition that jeopardized the health of a single animal.

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

Sincerely,
(b) (6)

