



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

October 18, 2021

Re: Animal Welfare Assurance
#A3245-01 (OLAW Case 4H)

Dr. Melur K. Ramasubramanian
Vice President for Research
Professor, Mechanical Engineering
University of Virginia
Box 400301
Charlottesville VA 22904-4301

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 15, 2021 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 August 30, 2021. According to the information provided, OLAW understands that post-operative care and recordkeeping was inadequate for post-surgical mice. Specifically, cage cards were incomplete for post-operative observations and analgesia administration. This failure occurred despite retraining, constituted noncompliance with institutional policy and the protocol, and had the potential to negatively impact animal welfare.

The corrective actions consisted of counseling the Principal Investigator and retraining the laboratory staff. The PI will ensure that post-operative observations are performed and that analgesics are administered and the PI will check the cage cards regularly. An enhanced surgical and post-operative log sheet will also be used.

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 Welfare Compliance Report
PHS Assurance # A3245-01

The Institutional Animal Care and Use Committee found 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 Angela Gamble, Director of the Office of Animal Welfare. 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 #: 2021-Q

Nature of Incident(s):	Failure to adhere to approved protocol resulting in inadequate post-operative care; failure to maintain appropriate animal-related records (mice)
Summary of Incident:	The veterinary staff reported to the Office of Animal Welfare (OAW) that surgery cage cards were found incomplete after additional training had been provided. The cards were incomplete for post-operative observations and analgesia administration.
Action taken by IACUC:	The IACUC discussed the incident at the next convened meeting and determined that the incident was a significant deficiency because of the <i>potential</i> impact on animal welfare and the deviation from the protocol and IACUC policy. The issue was previously addressed with the PI and the IACUC followed the next step in the sanction policy. The IACUC sent a letter to the PI notifying him of the deficiency and required a written corrective action plan to prevent reoccurrence. The chair of the PI's department was copied on the correspondence.
Action taken by PI:	<p>The PI responded to the IACUC concerns. Based on the information in the letter, the OAW Director attended the next convened laboratory meeting with the PI and his animal handlers. The OAW Director discussed the compliance issues and retrained the group regarding completion of surgery cage cards and surgical logs. Additional methods for improving compliance were discussed with the PI and animal handlers.</p> <p>The PI outlined his corrective action plan for resolving the issues. He had been unclear on the expectations of the policy and following retraining will ensure that the policy is followed. The Director of the OAW reviewed documentation and determined that analgesia <i>had</i> been given appropriately even though it was not documented appropriately on the surgery cage cards. The PI will train all new animal handlers assigned to perform surgical experiments to ensure compliance. The PI implemented additional checks within the laboratory to ensure that post-operative observations are performed as required. The PI will perform checks of the surgery cage cards weekly and discuss any issues</p>

	during their weekly laboratory meeting. Surgeons will be permitted to work independently after competency is demonstrated.
Action taken by IACUC:	The IACUC felt that the PI responded appropriately and no further action was deemed necessary. The OAW provided retraining to members of the laboratory and attendance was documented. The IACUC reviewed and approved the PI's enhanced surgical and post-operative log sheet.
Decision/Resolution:	The IACUC accepted the corrective action plans and considered the incident resolved.
Federal Funding:	K22NS104392
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	<div style="background-color: #cccccc; width: 100%; height: 1.2em; display: flex; justify-content: flex-end; align-items: center; padding-right: 5px;">(b) (6)</div> Date: 15 Oct 2021

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 15, 2021 8:41 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report

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

From: (b) (6)
Sent: Friday, October 15, 2021 7:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Ramasubramanian, Melur K (mkr5a) <mkr5a@virginia.edu>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; Gamble, Angela (adr8s) <adr8s@virginia.edu>
Subject: FW: 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 a compliance report from our IACUC. This is our case 2021-Q; a preliminary report was submitted.

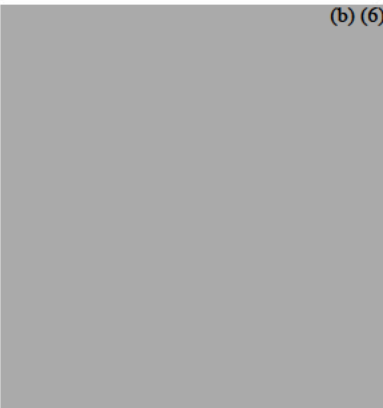
In this case, the IACUC has investigated thoroughly, taken appropriate action and the committee has determined that this matter is now resolved to their satisfaction.

I have reviewed the report and I concur with the committee response and final determination.

Thank you,
(b) (6)

For Dr. Melur Ramasubramanian

(b) (6)



Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 1, 2021 7:27 AM
To: Gamble, Angela (adr8s)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01). Case 2021-Q

Thank you for this preliminary report, Ms. Gamble. We will open a new case file.

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

From: Gamble, Angela (adr8s) <adr8s@virginia.edu>
Sent: Monday, August 30, 2021 3:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: Gamble, Angela (adr8s) <adr8s@virginia.edu>; (b) (6)
Subject: preliminary notification - UVA (Assurance A3245-01). Case 2021-Q

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 during an assessment of the program. The UVA tracking number is listed below. 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.

- 2021-Q: post-operative care was inadequate and appropriate animal records were not maintained

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

Sincerely,
 Angela Gamble

Angela R. Gamble
 Director, Office of Animal Welfare

E: adr8s@virginia.edu
P: (b) (6)

University of Virginia
Office of Animal Welfare
 Box 800720
 Charlottesville, VA 22908
<https://research.virginia.edu/office-animal-welfare>

