



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

October 28, 2022

Re: Animal Welfare Assurance  
#A3245-01 [OLAW Case 40]

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 October 25, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia. According to the information provided, OLAW understands that three post-operative mice were noted to have incomplete surgery cage cards. Not all analgesics administered had been listed and not all required post-operative observations had been recorded. Assessment by the veterinarian determined that the mice were doing well.

The corrective actions consisted of retraining the surgeon, laboratory staff, and animal caretakers on documenting administration of analgesia, post-operative observation frequency, maintenance of surgery logs, proper use of surgery cage cards, institutional surgical policy, and the protocol. The protocol was amended following consultation with the Attending Veterinarian regarding the analgesic regimen.

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. Due to the timing of the discovery, investigation, and resolution, a preliminary report was not submitted. This document is a summary of the incident, actions taken, and final resolution.

**UVA Compliance Case #: 2022-H**

<b>Nature of Incident(s):</b>	Failure to adhere to approved protocol resulting in inadequate post-operative care; failure to maintain appropriate animal-related records. (mice)
<b>Summary of Incident:</b>	During an assessment in the vivaria, a member of the Institutional Animal Care and Use Committee (IACUC) observed three animals with incomplete surgery cage cards. The cards were incomplete for the required number of post-operative observations and analgesia administration. One of two required analgesics were documented as being administered. According to the veterinarian, the animals appeared to be okay at the time of the assessment.
<b>Action taken by IACUC:</b>	The IACUC discussed the incident at a 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 Office of Animal Welfare (OAW) conducted a survival surgery seminar for research staff and the surgeon was in attendance. The following were reviewed during the seminar: post-operative observation frequency based on surgery; documenting administration of analgesia, maintaining surgery logs, and proper use of surgery cage cards. The IACUC sent a letter to the PI notifying him of the deficiency and required a written corrective action plan to prevent reoccurrence.
<b>Action taken by PI:</b>	The PI responded to the IACUC concerns. In addition to the surgeon attending the specialized surgical seminar, the PI discussed the issue with all animal handlers and retrained everyone regarding the number of post-operative observations to perform and the proper way to complete surgery cage cards. They also reviewed the IACUC surgical policy and protocol. The surgeon indicated that the animals had been observed for the required number of days; however, he failed to document all observations. The PI reviewed the analgesic regimen listed in the protocol with the Attending Veterinarian. The PI submitted modifications to the protocol based on the veterinary consultation.
<b>Action taken by IACUC:</b>	The IACUC felt that the PI responded appropriately and no further action was deemed necessary. The modifications to the protocol were reviewed and approved by the IACUC.
<b>Decision/Resolution:</b>	The IACUC accepted the corrective action plans as submitted by the PI and considered the incident resolved.
<b>Federal Funding:</b>	NIH R01HL108609

<b>Notification of Final Disposition:</b>	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
<b>Institutional Official:</b> Dr. Melur K. Ramasubramanian	<div style="background-color: gray; width: 100px; height: 15px; display: inline-block;"></div> (b) (6) Date: October 25, 2022

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, October 25, 2022 12:40 PM  
**To:** [REDACTED] (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: UVA - OLAW Compliance Notes

Good afternoon [REDACTED] (b) (6)

Thank you for sending us these six reports and we will send official responses 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:** Tuesday, October 25, 2022 10:05 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] UVA - OLAW Compliance Notes

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 six compliance reports from our IACUC. These are 2022-H, 2022-I, 2022-J, 2022-P, 2022-Q and 2022-S.

As described in the reports, preliminary reports were not submitted.

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

[REDACTED] (b) (6) on behalf of Ram Ramasubramanian

[REDACTED] (b) (6)

*Vice President for Research*

(b) (6)

University of Virginia  
Office of the VP for Research  
Varsity Hall  
136 Hospital Drive  
Box 400301  
Charlottesville, VA 22904  
<https://research.virginia.edu/>

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