



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

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October 28, 2022

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

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 found with incomplete surgery cage cards. There was no documentation of the required number of post-operative observations or analgesia administration. Analgesia had been given and the veterinarian found the mice to be in good condition.

The corrective actions consisted of retraining the research staff and surgeon on documenting analgesia administration, post-operative observation frequency, maintenance of surgery logs, and proper use of surgery cage cards. The Principal Investigator updated the laboratory standard operating procedures to clarify post-operative observations and documentation of analgesia administration, and staff was trained on the updates. Surgeons will be responsible for ensuring adequate post-operative oversight for their animals.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We note that because the issue of inadequate recordkeeping and post-operative responsibilities appears to be prevalent in various studies involving different species and laboratories, that a program-wide corrective approach may be necessary. The investigator training program may need to emphasize the importance of these issues and post-approval monitoring should continue to be applied to identify such deficiencies. We appreciate having been informed of this matter and find no cause for further action by this Office.

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-J

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:	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 card was incomplete for the required number of post-operative observations and analgesia administration. Upon documentation review, adequate analgesia was administered but failure in proper documentation procedures. According to the veterinarian, the animals appeared to be okay at the time of the assessment.
Action taken by IACUC:	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 IACUC policy. According to the surgery log sheet, adequate and proper analgesia was administered but the surgeon failed to document administration on the surgery cage card. 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.
Action taken by PI:	The PI responded to the IACUC concerns. The surgeon attended the specialized surgical seminar. The PI updated the internal surgical standard operating procedures to enhance the instructions for the number of required post-operative observations including documenting administration of analgesia. The PI retrained everyone regarding the updated procedures. The PI no longer permitted sharing tasks amongst surgeons and in the future each surgeon will be responsible for their post-operative animals for the duration of the post-operative period.
Action taken by IACUC:	The IACUC felt that the PI responded appropriately and no further action was deemed necessary.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and considered the incident resolved.
Federal Funding:	NIH 1R01NS091617-06

Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	(b) (6)
	Date: October 25, 2022

McCoy, Devora (NIH/OD) [E]

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

Good afternoon (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: (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: (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.

(b) (6) on behalf of Ram Ramasubramanian

(b) (6)

Vice President for Research

(b) (6)

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