



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

October 28, 2022

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

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 birds had undergone surgery, but the cage cards did not reflect the number of post-operative observations or analgesia administration. Analgesics had been administered and the veterinarian found the animals to be in good condition. This study is supported by NSF grant #ISO-1942480.

The corrective actions consisted of retraining the research staff and surgeons on post-operative observation frequency, documentation of analgesia administration, maintenance of surgery logs, and proper use of surgery cage cards. The animal caretakers were retrained on conducting animal observations, identifying and addressing pain/distress, and recordkeeping. Weekend responsibilities were also covered with the animal care staff and surgeons and the Principal Investigator will enhance oversight of the study.

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
Dr. Floh Thiels, NSF

**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-P

Nature of Incident(s):	Failure to adhere to approved protocol resulting in inadequate post-operative care; failure to maintain appropriate animal-related records. (birds)
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. The Office of Animal Welfare (OAW) conducted a survival surgery seminar for research staff and the surgeons (2) were 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:	<p>The PI responded to the IACUC concerns. The surgeons attended the specialized surgical seminar. The PI indicated that administering analgesia is included in the standard operating procedure for performing the surgery and said the analgesia was administered. They were not aware that the analgesia must be documented on the surgery cage card within the initial observation. The PI indicated that the individual performing the husbandry tasks in the room is also responsible for observing post-operative animals. The PI felt that the person responsible for performing the husbandry has failed to document their observations.</p> <p>The PI communicated the IACUC's concerns immediately with his staff and retrained all animal handlers on how to perform the following: observations, identify signs of pain and or distress, address and report signs of pain and or distress, required frequency of observations, and proper documentation. The weekend duties and post-operative observations required on the weekends was also</p>

	<p>reviewed and expectations were outlined for all animal handlers. Surgeons will be responsible for checking post-operative animals following a weekend to ensure completeness of documentation. The PI indicated that oversight would also be enhanced. He will perform weekly checks for a minimum of three months to ensure compliance and will address issues upon discovery.</p>
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:	NSF: ISO-1942480
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	<p style="text-align: right;">(b) (6)</p> <p>Date: October 25, 2022</p>

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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