



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 4S]

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 cage cards for three post-operative mice did not reflect the required number of post-operative observations or provision of analgesia. Veterinary assessment of the animals found them to be in good condition.

The corrective actions consisted of retraining the surgeon and staff on post-operative observation frequency, appropriate documentation of analgesia, maintenance of surgery logs, and proper use of surgery cage cards. The surgeon was counseled by the Principal Investigator (PI) on following institutional policies on animal observations and recordkeeping. Additional faculty will oversee laboratory staff in the PI's absence.

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-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:	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. The method used to document analgesia was inappropriate. 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 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.
Action taken by PI:	The PI responded to the IACUC concerns. In addition to the surgeon attending the specialized surgical seminar, the PI discussed the issue with the surgeon following the training. He ensured that animals would be observed and documented in accordance with the IACUC policy. He also reviewed the proper way to document analgesic administration. The PI has additional faculty to oversee the animal work being performed on the protocol on occasions of his absence from the laboratory.
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 R01 MH116694-01
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW

Institutional Official: Dr. Melur K. Ramasubramanian	<div data-bbox="613 147 1101 226" style="background-color: #cccccc; width: 300px; height: 38px;"></div> <div data-bbox="1101 147 1458 226" style="text-align: right;">(b) (6)</div> <div data-bbox="613 226 1458 277" style="text-align: center;">Date: October 25, 2022</div>
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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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