



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) 402-7065

October 21, 2019

Re: Animal Welfare Assurance
#A3245-01 (OLAW Case 3T]

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 21, 2019 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 28, 2019. According to the information provided, OLAW understands that rats were not given analgesic as per protocol and that the laboratory records had been falsified to show that the drugs had been given. The individual responsible felt that giving opioid analgesic caused problems with recovery.

The corrective actions consisted of suspending the animal use privileges of the animal handler responsible. The Principal Investigators (PI) on the protocols involved reviewed and modified their protocols as needed, ensured that analgesia is given, assigned another animal handler to record analgesia administration, reviewed the rodent surgery policy, and separated recordkeeping for each PI. The Institutional Animal Care and Use Committee (IACUC) approved the protocol amendments, required a longer retention period for controlled drug records, and reinstated the animal handler following the suspension period.

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 IACUC 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
Director, Office of Animal Welfare

UNIVERSITY OF VIRGINIA
ANIMAL WELFARE COMPLIANCE REPORT

PHS Assurance # A3245-01

A preliminary email notification was sent to Dr. Brent Morse of OLAW by Angela Gamble, Director of the Office of Animal Welfare. It was understood that a full report would follow IACUC investigation. This document is a summary of the incident, actions taken, and final resolution.

UVA Compliance Case #: 2019-M (PI)
2019-N (PI)

Nature of Incident(s):	Failure to adhere to approved protocols resulting in inadequate post-operative care; failure to maintain appropriate animal-related records (rats)
Summary of Incident:	During a laboratory visit, an animal handler provided surgery cage cards and laboratory notebook documentation demonstrating post-operative analgesic administration (opioid). After the laboratory visit, the Office of Animal Welfare later determined that the animal handler failed to administer post-operative analgesia to animals receiving two types of survival surgeries. The animal handler had surgical responsibilities for two PIs. It was discovered that during the laboratory visit, the animal handler provided misleading statements, specifically indicating that the animals had received opioid analgesia and presented falsified records to support the statements. Later during the follow up investigation, the animal handler admitted to not providing the opioid and falsifying the surgery cage cards and laboratory notebook. The animal handler said that s/he felt that the opioid caused the animals not to recover properly therefore requiring euthanasia. S/he felt that withholding the opioid improved the recovery of the post-operative animals.

Action taken by IACUC	At the next convened meeting, the IACUC discussed the incident and was deeply concerned. They determined that the failure to administer analgesia to animals, deviations from the protocols, violation of the IACUC rodent survival surgery policy, and misleading the IACUC were each significant issues requiring correction. The animal handler that misled the IACUC also is the individual who primarily updates and submits the protocols on behalf of the PIs; therefore the significant deviations from the protocol appeared not to be related to being unfamiliar with protocol contents. Animal handler did not use established means for modifying the protocol(s) to address any complications s/he experienced with the use of analgesics. IACUC depends on the truthfulness of animal handlers and falsification of documentation and misleading statements was considered unacceptable. The IACUC voted to suspend the animal handler for a minimum of 90 days. The PIs were sent a joint letter from the IACUC regarding their concerns and required a written corrective action plan. In addition to the plan, the IACUC required several additional components to be addressed and resolved: the PIs and animal handlers were required to adhere to the specifics written in the protocol and make certain that they are followed as written; the protocols must be reviewed for accuracy and submit modifications as needed; provide method for validating the administration of analgesia independent of the individual animal handler that was suspended; review the surgery policy; ensure that records and documentation are complete.
Action taken by PIs jointly:	The PIs provided a joint written corrective action plan. The plan included the following: all protocols were thoroughly reviewed and modifications were submitted as needed; they will ensure that analgesia is administered as written; they assigned an animal handler to confirm and record analgesia administration by the animal handler that had been suspended; they reviewed the rodent surgery policy; and they separated the recordkeeping and documentation specifically by PI instead of maintaining a combine record. After the 90 day suspension, the PIs petitioned the IACUC for reinstatement of animal privileges for the particular animal handler.
Action taken by IACUC:	The protocols were approved as modified. The IACUC felt that the PIs responded appropriately. The IACUC required additional usage records for the controlled substances beyond the state recordkeeping requirements. Once the 90 day period was complete, the IACUC reviewed and approved the petition for reinstatement. No further action was deemed necessary.
Decision/Resolution:	The IACUC considered the incident resolved.
Federal Funding:	1R01HL128189-01A1; 1R01DK110369-01

Notification of Final Disposition:	<input checked="" type="checkbox"/> IO	<input checked="" type="checkbox"/> OLAW	<input type="checkbox"/> AAAAC
---	--	--	--------------------------------

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 21, 2019 10:53 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UVA OLAW Compliance Report 2019-M; 2019-N

Thank you for these reports, (b) (6) We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Monday, October 21, 2019 10:32 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>; (b) (6) Ramasubramanian, Melur K (mkr5a) <mkr5a@virginia.edu>; Gamble, Angela (adr8s) <adr8s@virginia.edu>
Subject: UVA OLAW Compliance Report 2019-M; 2019-N

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. These are our cases 2019-M and 2019-N.

In this cases, 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.

Regards,
Ram

(b) (6)
For Melur K. Ramasubramanian
Vice President for Research

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 29, 2019 6:31 AM
To: Gamble, Angela (adr8s)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01): 2019-M and 2019-N

Thank you for this report, Ms. Gamble. We will start a new case file.
Axel Wolff

From: Gamble, Angela (adr8s) <adr8s@virginia.edu>
Sent: Wednesday, August 28, 2019 11:44 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.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): 2019-M and 2019-N

Dear Drs. Wolff and Morse,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) has identified a significant deficiency involving two researchers. The single event has two IACUC Tracking Numbers (2019-M and 2019-N) due to the dual involvement. The issue is under investigation and review by the IACUC. Specifically, it appears that post-operative care was inadequate and appropriate animal records were not maintained. We are working with the PIs towards resolution and will send you a complete report once it has been resolved.

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

Sincerely,
Angela Gamble

Angela Gamble
University of Virginia
Director, Office of Animal Welfare
Charlottesville, VA 22908
PH: (b) (6)