



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
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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

September 22, 2021

Re: Animal Welfare Assurance
#A3245-01 (OLAW Case 4F]

Dr. Melur Ramasubramanian
Vice President for Research
University of Virginia
P.O. Box 400301
136 Hospital Drive, (b) (4)
Charlottesville, VA 22904-4301

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 8, 2021 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 July 21, 2021 notification by email.

According to the information provided, this Office understands that the University of Virginia Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol and failure to maintain appropriate animal-related records. The final report states an IACUC member identified two cages of animals (mice) with incomplete surgery cage cards during an assessment in the vivarium. The cards were incomplete for post-operative (post-op) observations and administration of analgesia.

The matter was discussed by the IACUC and determined to be a significant deficiency and deviation from the protocol and IACUC policy. Per the report, it appeared the surgeon was not adequately trained to complete the surgery cage cards, and it was later confirmed that post-op analgesia had not been administered. In response, the committee sent a letter to the principal investigator (PI) informing them of the incident and a corrective action plan was requested by the IACUC.

The PI responded to the IACUC with the following corrective action plan:

- The PI will train all new animal handlers assigned to perform surgical experiments to ensure compliance and they will not be permitted to work independently until competency is demonstrated.
- A senior animal handler will visit the vivarium on a routine basis and examine surgery cage cards for completion.
- The laboratory will review portions of the animal use protocol on a routine basis to ensure familiarity with approved procedures.
- The analgesic regimen in the approved protocol will be followed until modifications are submitted and approved.
- The laboratory consulted with the Attending Veterinarian to determine if modifications to the protocol were warranted.

The IACUC determined the corrective action plan provided by the PI was appropriate and concluded no further action was necessary.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Virginia has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 – Dr. Ramasubramanian
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OLAW Case A3245-4F

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

**Jacquelyn
T. Tubbs -S**

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2021.09.22
08:53:31 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

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. A preliminary email notification was sent to the OLAW Division of Compliance Oversight by Angela Gamble, Director of the Office of Animal Welfare. Dr. Axel Wolff acknowledged receipt. It was understood that a full report would be submitted following an IACUC investigation. This document is a summary of the incident, actions taken, and final resolution.

UVA Compliance Case #: 2021-N

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 two cages of animals with incomplete surgery cage cards. The cards were incomplete for post-operative observations and analgesia administration.
Action taken by IACUC:	The IACUC discussed the incident at the Program Review 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. It appeared that the surgeon was not adequately trained to complete the surgery cage cards, and it was unclear if post-operative analgesia was administered in accordance with the approved protocol. 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 and indicated that the animal handlers were retrained on the proper way to complete surgery cage cards and reviewed the IACUC surgical policy. The PI will train all new animal handlers assigned to perform surgical experiments to ensure compliance and they will not be permitted to work independently until competency is demonstrated. A senior animal handler will visit the vivarium on a routine basis and examine surgery cage cards for completion. The laboratory will review portions of the animal use protocol on a routine basis to ensure familiarity with approved procedures. The analgesia had not been administered at the frequency listed in the approved protocol. The analgesic regimen in the approved protocol will be followed until modifications are submitted and approved. The laboratory consulted with the Attending Veterinarian to determine if modifications to the protocol were warranted.

Action taken by IACUC:	The IACUC felt that the PI responded appropriately and no further action was deemed necessary. This incident occurred during the COVID-19 pandemic which may have contributed to the occurrence. Upon examination of the colony with respect to the corrective action plan success, the Office of Animal Welfare found all cages to be compliant.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and considered the incident resolved.
Federal Funding:	R01HL142808
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	<div style="background-color: #cccccc; padding: 5px;">(b) (6)</div> Date: 8 Sep2021

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 8, 2021 9:14 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UVA OLAW Report

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

From: (b) (6)
Sent: Wednesday, September 8, 2021 9:01 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 Report

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 five compliance reports from our IACUC. These are our cases 2021-H, 2021-I, 2021-J, 2021-K, 2021-N, 2021-O and 2021-T. Preliminary reports were submitted for all except 2021-T. This matter was self-reported by the Attending Vet and his report included both his investigation and his corrective action plan, and as a result there really wasn't time to submit the preliminary report.

In these cases, the IACUC has investigated thoroughly, taken appropriate action and the committee has determined that these matters are now resolved to their satisfaction.

I have reviewed the report and I concur with the committee responses and final determinations.

Thank you,

(b) (6)

For Melur K. Ramasubramanian

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 23, 2021 7:32 AM
To: Gamble, Angela (adr8s)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary notification - UVA (Assurance A3245-01)

Thank you for these reports, Ms. Gamble. We will open new case files and look forward to receiving the final report from the IO after the IACUC has completed the investigations.

Axel Wolff, M.S., D.V.M.
 Deputy Director, OLAW

From: Gamble, Angela (adr8s) <adr8s@virginia.edu>
Sent: Wednesday, July 21, 2021 5:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6) Gamble, Angela (adr8s) <adr8s@virginia.edu>
Subject: preliminary notification - UVA (Assurance A3245-01)

Dear OLAW Division of Compliance Oversight,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified several significant deficiencies during an assessment of the program. The UVA tracking numbers are listed below. The issues with two tracking numbers involve two researchers. Each issue is currently under investigation and review by the IACUC. We are working towards resolution and will send a separate compliance report for each of the bulleted points once resolved.

- 2021-H and 2021-I: condition that *potentially* jeopardized the health or well-being of animals resulting in the *potential* for harm or death (neonatal mice). This single event has two IACUC Tracking Numbers due to the dual involvement of two separate investigators.
- 2021-J and 2021-K: condition that *potentially* jeopardized the health or well-being of animals resulting in the *potential* for harm or death (neonatal mice) This single event has two IACUC Tracking Numbers due to the dual involvement of two separate investigators.
- 2021-N: post-operative care was inadequate and appropriate animal records were not maintained
- 2021-O: condition that had the *potential* to jeopardize the health or well-being of an animal (mice)

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

Sincerely,
 Angela Gamble

Angela R. Gamble
 Director, Office of Animal Welfare

E: adr8s@virginia.edu
 P: (b) (6)

University of Virginia
Office of Animal Welfare
Box 800720
Charlottesville, VA 22908
<https://research.virginia.edu/office-animal-welfare>

