



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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 4E)

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 institutional policies/procedures and conditions that jeopardized the well-being of animals with the potential for harm to animals. The report states an IACUC member identified a cage of breeding animals (mice) that had not been separated in accordance with the IACUC breeding and weaning policy. The principal investigator (PI) and husbandry staff failed to remove the older litter and dam from the cage. It is understood that if a PI fails to separate animals appropriately, IACUC policy requires that the husbandry staff separate animals.

The incident was discussed by the IACUC and determined to be a significant deficiency and deviation from the IACUC policy. In response, the IACUC sent a letter to the PI and Attending Veterinarian (AV) informing them of the deficiency and provided the policy to review with staff. The committee also requested a corrective action plan from both the PI and the AV. The PI provided the following corrective action plan:

- The issue was discussed and reviewed with the animal handlers on the protocol.
- The breeding policy will be reinforced more rigorously to both new and existing animal handlers.
- The specific criteria for trio breeding was emphasized to existing animal handlers.
- All animal handlers required to review their breeding and experimental cages at least once every two days.
- The PI will inspect the rodent colony twice weekly to ensure compliance.
- A laboratory handbook is being written and will detail animal husbandry practices and procedures. The breeding policy will be highlighted in the handbook.

The report states the AV met with the husbandry staff and reviewed the policy and the shared responsibility between the husbandry and research staff. The AV emphasized animal well-being and reviewed the circumstances requiring the use of a breeding exemption to delay weaning small pups. The IACUC determined the actions of the PI and AV were appropriate and required no further actions.

It is noted that these animals are 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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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 08:46:12
-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-J (PI)
 2021-K (husbandry staff)

Nature of Incident(s):	Condition that potentially jeopardized the health or well-being of an animal resulting in the potential for harm (mice).
Summary of Incident:	During an assessment in the vivaria, a member of the Institutional Animal Care and Use Committee (IACUC) observed one cage of breeding animals wherein the PI and husbandry staff failed to remove the older litter and dam from the cage in accordance with the IACUC breeding and weaning policy. In the event that a PI fails to separate animals appropriately, IACUC policy requires that the husbandry staff to separate animals.
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 neonatal animal welfare and the deviation from IACUC policy. The litters were greater than seven days apart in birth. The IACUC sent a letter to both the PI and Attending Veterinarian (AV) notifying them of the deficiency and provided the policy to review with the staff. Both the PI and AV were required to respond in writing with a corrective action plan to prevent reoccurrence with staff members (researchers and animal husbandry staff).
Action taken by PI:	The PI responded to the IACUC concerns and indicated that the issue was discussed and reviewed with the animal handlers on the protocol. The breeding policy will be reinforced more rigorously to both new and existing animal handlers. The specific criteria for trio breeding was emphasized to existing animal handlers. The PI requires that all of his animal handlers review their breeding and experimental cages at least once every two days. The PI will inspect the rodent colony twice weekly to ensure compliance. A laboratory handbook is being written and will detail animal husbandry practices and procedures. The breeding policy will be highlighted in the handbook.
Action taken by AV:	The AV responded with a corrective action plan. The AV met with the husbandry staff and reviewed the policy and the shared responsibility between the husbandry and research staff. He emphasized animal well-being as the focus of the policy and

	reviewed circumstances requiring the use of a breeding exemption to delay weaning small pups.
Action taken by IACUC:	The IACUC felt that the PI and AV 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 re-examination of the colony with respect to the corrective action plan success, the Office of Animal Welfare found all breeding cages to be compliant; however, the IACUC reminded the PI that the husbandry staff will separate and or wean cages in accordance with the policy. A punitive fee will be charged for cages that the husbandry staff separate. The PI acknowledged the requirement and reinforced the requirements with his animal handlers.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and AV and considered the incident resolved.
Federal Funding:	R01DC018842
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	(b) (6) Date: 8 Sep 2021

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>

