



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

March 29, 2021

Re: Animal Welfare Assurance
#A3245-01 (OLAW Case 4B)

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

Dear Dr. Ramasubramanian,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 18 March 2021 report of an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Virginia [UVA Compliance Case #: 2021-A (PI) and 2021-B (husbandry staff)]. According to the information provided it is understood that one cage of breeding mice was found 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. The related animal activity was PHS funded.

Corrective and preventive actions included the PI discussing the incident and corrective action plan with the animal handler who maintains the colony. Breeding cages will be examined at least four days/week and separated in accordance with policy. The vivarium facility supervisor retrained the animal husbandry staff regarding their responsibility for separating animals when the research staff fails to do so.

OLAW believes that the corrective and preventive measures put in place by the University of Virginia are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2021.03.29 15:16:16 -04'00'

Brent C. Morse, DVM
Director
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. Due to the rapid nature of the discovery and subsequent resolution, a preliminary email notification was not sent to the OLAW Division of Compliance Oversight. This document is a summary of the incident, actions taken, and final resolution.

UVA Compliance Case #: 2021-A (PI)
 2021-B (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, the husbandry staff is required to separate animals. There was <i>no</i> evidence of pup loss.
Action taken by IACUC:	The IACUC discussed the incident at the Program Review meeting and determined that 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 pointed out that this was the first issue noted in the 12-year history of maintaining animals at the institution. The PI discussed the incident and corrective action plan with the animal handler who maintains the colony. Breeding cages will be examined at least four days/week and separated in accordance with policy. Room audits will occur before 2pm to ensure that caging supplies are easily accessible and/or request assistance from husbandry staff.
Action taken by AV:	The AV responded with a corrective action plan. The vivarium facility supervisor retrained the animal husbandry staff regarding their responsibility for separating animals when the research staff fails to do so. The animal caretaker responsible for the room was a newer employee. They reviewed the IACUC breeding and weaning policy and

	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 and 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 breeding cages to be compliant.
Decision/Resolution:	The IACUC accepted the corrective action plans as submitted by the PI and AV and considered the incident resolved.
Federal Funding:	1R01DK119182-01A1
Notification of Final Disposition:	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW
Institutional Official: Dr. Melur K. Ramasubramanian	<div style="background-color: gray; width: 100%; height: 1.2em; display: flex; justify-content: flex-end; align-items: center; padding-right: 5px;">(b) (6)</div> Date: 18 March 2021

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 19, 2021 7:21 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UVA OLAW Compliance Report 2021-A; 2021-B

Thank you for this report. We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Thursday, March 18, 2021 10:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; (b) (6) Ramasubramanian,
(b) (6) Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Subject: UVA OLAW Compliance Report 2021-A; 2021-B

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 is our case 2021-A and 2021-B

In this case, the IACUC has investigated thoroughly, taken appropriate action and the committee has determined that this matter are now resolved to their satisfaction.

I have reviewed the report and I concur with the committee response and final determination.

Thank you,
(b) (6)

For Dr. Melur Ramasubramanian

(b) (6)

