



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
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February 13, 2019

Re: Animal Welfare Assurance  
#A3245-01 (OLAW Case 3P)

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 February 12, 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 November 14, 2018. According to the information provided, OLAW understands that some neonatal mouse pups died because the older litter in the cage had not been removed before the new litter was born. Institutional policy states that if mice are not separated by the Principal Investigator, then the animal care staff is to do so.

The corrective actions consisted of the Principal Investigator reviewing the breeding and weaning policy with the research staff members, who agreed to separate litters as required. If weaning is delayed due to developmental problems with the pups, a weaning exemption will be submitted. The Attending Veterinarian counseled the animal facility supervisor to ensure that caretakers follow the breeding and weaning policy and to work with the research staff regarding weaning exemptions.

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  
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 #:** 2018-N (PI)  
2018-O (husbandry staff)

<b>Nature of Incident(s):</b>	Condition that jeopardized the health and well-being of animals resulting in neonatal deaths (mice)
<b>Summary of Incident:</b>	During the semi-annual inspection, inspectors observed one cage of breeding animals in violation of the IACUC breeding and weaning policy wherein the PI and husbandry staff failed to remove the older litter from the cage before a new litter was born resulting in deaths of the neonatal pups. In the event that a PI fails to separate animals appropriately, the husbandry staff is required to separate animals.
<b>Action taken by IACUC:</b>	A sub-committee of the IACUC met with the PI to discuss the inspection findings and gather additional information. The IACUC discussed the incident at the Program Review meeting and determined that incident was a significant deficiency because of the impact on neonatal animal welfare and the deviation from IACUC policy. 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).
<b>Action taken by PI:</b>	The PI responded to the IACUC concerns and identified methods for correction. The PI was very concerned about the finding and reviewed the incident and the details of the breeding and weaning policy with his staff. They will ensure that there are never two separate litters in one breeding cage. He confirmed with his staff that this was a very unusual incident, and he felt that it may have been due to miscommunication between the research staff and husbandry staff. It is laboratory policy to wean animals on Day 21 and if a litter requires a delay in weaning due to aberrant development, they will request the exemption on the appropriate delayed weaning exemption log sheet in accordance with IACUC policy.

<b>Action taken by AV:</b>	The AV responded with a correct action plan. The AV met with the vivarium facility supervisor and reminded her that the vivarium staff need to adhere to the IACUC policy and work collaboratively with the research staff when a weaning exemption is necessary.
<b>Action taken by IACUC:</b>	The IACUC felt that the PI and AV responded appropriately and no further action was deemed necessary.
<b>Decision/Resolution:</b>	The IACUC accepted the corrective action plans as submitted by the PI and AV and considered the incident resolved.
<b>Federal Funding:</b>	R01GM11937
<b>Notification of Final Disposition:</b>	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW <input type="checkbox"/> AAALAC

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A3245-3D

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, November 14, 2018 12:23 PM  
**To:** Gamble, Angela Rinker (adr8s); OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: preliminary notification of 2018-N - UVA (Assurance A3245-01)

Thank you for providing this preliminary report. We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Gamble, Angela Rinker (adr8s) [mailto:adr8s@virginia.edu]  
**Sent:** Wednesday, November 14, 2018 10:44 AM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Gamble, Angela Rinker (adr8s) <adr8s@virginia.edu>  
**Subject:** preliminary notification of 2018-N - UVA (Assurance A3245-01)

Dear Dr. Morse,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) identified a significant deficiency during our recent semi-annual inspection. Although still under investigation, the deficiency involved the failure to maintain a cage of breeding mice in accordance to the Breeding and Weaning Policy thus resulting in animal harm (neonatal death). The incident is under review by the IACUC, and we will be working with the PI and husbandry staff towards resolution. We will send you a complete report once the incident has been resolved. The IACUC tracking number for this incident is 2018-N.

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)