



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

September 22, 2021

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

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 document 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: conditions that had the potential to jeopardize the health and/or well-being of an animal. An IACUC member identified a mouse with a noted unresolved medical condition during an assessment in the vivarium. While the condition was recorded on the cage card, it had not been reported to the veterinary staff. In response, the animal was immediately evaluated and found to be bright, alert, and responsive. However, it is stated the animal should have been euthanized for the chronic unresolved condition.

The matter was discussed by the IACUC and determined to be a significant deficiency and programmatic issue since it had the potential to affect any animal at the institution. The IACUC requested a corrective action plan from the Attending Veterinarian (AV) regarding the deficiency. The AV met with the vivarium supervisor, and it was revealed the supervisor was unaware that the condition should have been reported to the veterinary staff for evaluation. It is also stated the chronic condition could not be effectively treated and that the laboratory should have been notified that euthanasia of the animal was necessary. It is understood the vivarium supervisor was informed that all animal health related conditions must be reported to the veterinary staff for evaluation. Per the report, the IACUC determined the AV responded appropriately and no further action was necessary.

It is noted that this animal was not 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.

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
08:58:17 -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-O

Nature of Incident(s):	Condition that had the potential to jeopardize the health or well-being of an animal (mouse).
Summary of Incident:	During an assessment in the vivaria, a member of the Institutional Animal Care and Use Committee (IACUC) observed one animal with a noted unresolved medical condition. The condition was noted on the cage card but had not been reported to the veterinary staff. The animal was immediately evaluated by a veterinarian, and found to be bright, alert, and responsive; however, the animals should have been euthanized for the chronic unresolved condition.
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 failure to report the animal health condition to the veterinary staff which then lead to inadequate veterinary care in addressing the chronic unresolved condition. Although only one animal was found, the IACUC considered it a programmatic issue that had the potential of affecting any animal at the institution (i.e., federally funded, institutionally funded). The IACUC wrote to the Attending Veterinarian (AV) describing the deficiency and required a response in writing with a corrective action plan to prevent reoccurrence.
Action taken by AV:	The AV responded with a corrective action plan. The AV met with the vivarium supervisor regarding the note on the cage indicating the medical condition. The vivarium supervisor was unaware that the condition should have been reported to the veterinary staff for evaluation. The AV explained to the vivarium supervisor that the veterinary technical staff should have had an opportunity to review the specific conditions. The chronic unresolvable condition that was noted during the assessment was identified as a condition that cannot be effectively treated; therefore, the laboratory should have been notified that the animal must be euthanized. The vivarium supervisor was told that all animal health related conditions must be reported to the veterinary staff for evaluation.

Action taken by IACUC:	The IACUC felt that the AV responded appropriately and no further action was deemed necessary.
Decision/Resolution:	The IACUC considered the incident resolved with no fault to any grant holder.
Federal Funding:	Not Applicable
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: Gamble, Angela (adr8s) <adr8s@virginia.edu>
Sent: Wednesday, July 21, 2021 5:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]
Cc: (b) (6) Gamble, Angela (adr8s)
Subject: preliminary notification - UVA (Assurance A3245-01)

Follow Up Flag: Follow up
Flag Status: Flagged

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>



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
- 2021O: 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>

