



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 26, 2020

Re: Animal Welfare Assurance  
#A3245-01 (OLAW Case 3U]

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 March 25, 2020 letter responding to OLAW's March 9, 2020 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia-Charlottesville. According to the information provided, OLAW understands that the details contained in the final report dated January 22, 2020 are accurate.

OLAW appreciates the prompt consideration of this matter by University of Virginia-Charlottesville, which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L.  
Lukovsky-  
akhsanov -S

Digitally signed by Nicole  
L. Lukovsky-akhsanov -S  
Date: 2020.03.26 10:40:03  
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact



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March 9, 2020

Re: Animal Welfare Assurance  
#A3245-01 (OLAW Case 3U]

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 January 22, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Virginia-Charlottesville. Your letter supplements the information provided in a preliminary report on January 8, 2020. According to the information provided, OLAW understands that the Office of Animal Welfare found expired analgesic had been administered to mice post-operatively. The animals had undergone intracranial injection followed by administration of one dose of expired analgesic and the animals were observed post-operatively with no signs of pain or distress as observed by animal handlers or vivarium staff.

Corrective actions included the IACUC sending a letter to the principal investigator (PI) reminding him of prohibition of use of expired analgesia for any purpose. The PI was required to properly disposed of the expired material and provide a written correction action plan to prevent recurrence and improve compliance. The PI created a redundant system for checking for expired materials in the lab including having three different individuals include the expiration dates of materials in their electronic calendar. When a new drug arrives, three individuals log the expiration date into their own respective calendar and will notify the individual two weeks prior to the material being expired. Additionally, the laboratory will hold weekly meetings to discuss matters associated with animal work.

OLAW appreciates the prompt consideration of this matter by University of Virginia-Charlottesville, which is consistent with the philosophy of institutional self-regulation. OLAW understands that information in preliminary reports is subject to change as details of the incident are investigated and clarified. Based on the information, OLAW is requesting clarification as the preliminary report references use of expired analgesic for euthanasia of animals which is different than the information presented in this report stating use of expired analgesia for use in post-operative procedures. Please send this clarification by **March 27, 2020** to [Nicole.Lukovsky@nih.gov](mailto:Nicole.Lukovsky@nih.gov) and identify **OLAW case # A3245-3U** in the documentation for ease of reference. We appreciate being informed of this matter and as always, do not hesitate to contact us with any questions or concerns.

Page 2 – Dr. Ramasubramanian  
March 9, 2020  
OLAW Case A3245-3U

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact

**University of Virginia**  
**Animal Welfare Compliance Report**  
 PHS Assurance # A3245-01

A preliminary email notification was sent to Dr. Brent Morse of OLAW by (b) (6).  
 (b) (6) 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 #: 2019-P**

<b>Nature of Incident(s):</b>	Condition that had the potential to jeopardize the health or well-being of animals. Specifically, the use of an expired analgesic following survival surgery (mice)
<b>Summary of Incident:</b>	The Office of Animal Welfare found that an expired analgesic had been administered to post-operative animals. The animals had undergone an intracranial injection followed by one dose of the expired analgesic. The animals were observed post-operatively and no signs of pain or distress were observed by the animal handlers or vivarium staff.
<b>Action taken by IACUC:</b>	The IACUC discussed the incident at the next convened monthly meeting. The IACUC sent the PI a letter reminding him that he is prohibited from using expired analgesia for any purpose. He was required to properly dispose of the expired materials and to provide a written corrective action plan to prevent reoccurrence. Due to the potential impact on animal welfare, the IACUC agreed that this was a significant deficiency.
<b>Action taken by PI:</b>	The PI provided a written corrective action plan to improve compliance and indicated that his staff inadvertently used the expired analgesia; however, the animals appeared not to suffer from pain or distress. The corrective action plan included the disposal of the expired analgesia and additional oversight. The lab will hold weekly laboratory meetings to discuss matters associated with animal work. The PI created a redundant system for checking for expired materials in the laboratory. Three different individuals have included the expiration dates of materials in their electronic calendar. When a new drug arrives, three individuals log the expiration date into their own respective calendar and will notify the individual two weeks prior to the material being expired.
<b>Action taken by IACUC:</b>	The IACUC accepted the corrective action plan, and no further action was deemed necessary.
<b>Decision/Resolution:</b>	Upon acceptance of the corrective action plan, the issue was considered resolved.
<b>Federal Funding:</b>	U01 CA220841
<b>Notification of Final Disposition:</b>	<input checked="" type="checkbox"/> IO <input checked="" type="checkbox"/> OLAW

*confirm analgesic vs. anesth. for euth.?*

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, January 22, 2020 2:47 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD); Wolff, Axel (NIH/OD) [E]  
**Cc:** (b) (6) Ramasubramanian, Melur K (mkr5a); (b) (6)  
**Subject:** RE: UVA OLAW Compliance Report case 2019-P

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

**From:** (b) (6)  
**Sent:** Wednesday, January 22, 2020 12:58 PM  
**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>; (b) (6)  
**Subject:** UVA OLAW Compliance Report case 2019-P

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. This is for our case 2019-P.

In this case, the IACUC has investigated thoroughly, taken appropriate action and the committee has determined that this matter is 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 Melur Ramasubramanian

(b) (6)

(b) (6)

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

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Thursday, January 09, 2020 7:14 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD); Wolff, Axel (NIH/OD) [E]  
**Cc:** (b) (6)  
**Subject:** RE: preliminary notification - UVA (Assurance A3245-01): 2019-P and 2019-Q/R

Thank you for submitting this report. We will open two separate cases and await the final reports.

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:** (b) (6)  
**Sent:** Wednesday, January 08, 2020 5:48 PM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** preliminary notification - UVA (Assurance A3245-01): 2019-P and 2019-Q/R

Dear Drs. Wolff and Morse,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) has identified two significant deficiencies, one of which involves two researchers. The two separate events occurred at the end of 2019, and the events are currently under investigation and review by the IACUC. We are working with each PI towards resolution, and we will send you a complete report for each event once it has been resolved. The reports will likely be sent separately based on the individualized timeline of resolution. The two separate events are listed below by IACUC Tracking Number.

- 2019-P: Use of an expired anesthetic solution for euthanasia of rodents
- 2019-Q and 2019-R: This single event has two IACUC Tracking Numbers due to the dual involvement of two separate investigators. The investigators share surgical animal handlers and it appears that post-operative care was inadequate and appropriate animal records were not maintained.

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

Sincerely,  
(b) (6)

(b) (6)