DEPARTMENT OF HEALTH & HUMAN SERVICES

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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) 402-7065

October 11, 2018

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

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 September 27, 2018 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 #: 2018-M). Your final report supplements the preliminary report sent via email on September 14, 2018. According to the information provided it is understood that expired anesthetic had been used to induce deep anesthesia prior to rapid euthanasia in mice. Depth of anesthesia had been verified via toe pinch prior to euthanasia. It was stated that the animals were assigned to a PHS-funded activity.

The corrective actions consisted of the PI providing the IACUC with a corrective action plan. This consisted of the PI counseling his laboratory staff regarding the concerns. The PI also improved drug usage and expiration documentation and created an automatic weekly email reminder for all lab members and then again the day prior to the expiration of substances administered to animals. The PI reviewed the new procedures with laboratory staff.

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,

(b) (6)

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

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-M

Nature of Incident(s):	Use of expired anesthesia (mice)
Summary of Incident:	During a follow-up visit, the Office of Animal Welfare (OAW) Compliance Associate found an expired bottle of anesthetic that had been used beyond the expiration date. A high dose of the anesthetic was used to induce deep anesthesia prior to rapid euthanasia. The depth of anesthesia had been verified prior to euthanasia via toe pinch. The expired anesthetic was used within 35 days of the listed expiration date.
Action taken by IACUC:	The OAW Director contacted the PI to discuss the finding and requested a corrective action plan to address the issue. The IACUC discussed the incident at the next convened monthly meeting and reviewed the corrective action plan provided by the PI. The IACUC determined that the incident was a significant deficiency due to the potential impact on animal welfare.
Action taken by PI:	The PI indicated that the laboratory had two bottles of anesthetic, and from his investigation, he determined that the laboratory staff inadvertently used the bottle of anesthetic that would have expired in 2019 first instead of the bottle expiring sooner in 2018. He acknowledged that regardless, the expired substance should not have been used, and he reviewed the concerns immediately with his laboratory staff. The PI submitted a corrective action plan for improved oversight which included: discarding the expired material; creating an inventory log sheet to include expiration dates; placing the log sheet in the drug storage location; placing an additional notification of expiration dates on the outside of the drug storage location; and creating an automatic email reminder that will be sent to all members of the laboratory once a week and then again one day prior to the expiration substances administered to animals. The PI reviewed the new procedures including the log sheet and reminded the staff to pay careful attention to expiration dates at the most recent laboratory meeting.

Action taken by IACUC:	The IACUC felt that the PI responded appropriately and no further action was deemed necessary.
Decision/Resolution:	The IACUC accepted the corrective action plan as submitted by the PI and considered the incident resolved.
Federal Funding:	HL108609
Notification of Final Disposition:	☒IO ☒OLAW ☐AAALAC

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 28, 2018 6:42 AM
To: (b) (6)
Subject: RE: UVA OLAW report

Thank you (b) (6) for this report. Dr. Wolff will respond soon.

Regards,
Joan

From: (b) (6)@virginia.edu>
Sent: Thursday, September 27, 2018 12:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E]
<wolffa@od.nih.gov>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: (b) (6)@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 Drive
Bethesda, MD

Dr. Wolff:

I attach a compliance report from our IACUC.

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

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

Best regards,
(b) (6)
For Melur K. (Ram) Ramasubramanian

Melur K. (Ram) Ramasubramanian, Ph.D.
Vice President for Research
Professor, Mechanical Engineering
University of Virginia
Box 400301
Charlottesville VA 22904-4301
(b) (6)(Office of VPR)
(Direct)
rammk@virginia.edu

Morse, Brent (NIH/OD) [E]

From:	Morse, Brent (NIH/OD) [E]
Sent:	Friday, September 14, 2018 1:18 PM
To:	Gamble, Angela Rinker (adr8s); OLAW Division of Compliance Oversight (NIH/OD)
Cc:	(b) (6)
Subject:	RE: preliminary notification of 2018-M - UVA (Assurance A3245-01)

Thank you for this preliminary report. We will open a case file and await the final report.

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: Gamble, Angela Rinker (adr8s) [mailto:adr8s@virginia.edu]
Sent: Friday, September 14, 2018 1:16 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)@virginia.edu>; Gamble, Angela Rinker (adr8s) <adr8s@virginia.edu>
Subject: preliminary notification of 2018-M - UVA (Assurance A3245-01)

Dear Dr. Morse,

This is to provide preliminary notification that the University of Virginia IACUC (PHS Assurance #A3245-01) has identified a significant deficiency related to the use of an expired anesthetic. The incident is under review by the IACUC, and we will be working with the PI towards resolution. We will send you a complete report once the incident has been resolved. The IACUC tracking number for this incident is 2018-M.

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)

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