



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

July 11, 2018

Re: Animal Welfare Assurance
A3448-01 [OLAW Case Y]

Dr. Yvonne T. Maddox
Vice President for Research and
Institutional Official
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814

Dear Dr. Maddox,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 22, 2018 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Uniformed Services University of the Health Sciences (USU), following up on an initial April 10, 2018 email notification. According to the information provided, OLAW understands that a Principal Investigator's associate performed an unauthorized procedure testing the concentration of an unapproved tribromoethanol anesthetic on four mice without prior IACUC approval. The responsible individual also failed to continuously monitor the animals until fully recovered, contrary to USU Standard Operating Procedures. Three of the mice were found dead and the remaining moribund animal was subsequently euthanized.

The corrective actions consisted of retraining the Principal Investigator (PI) and laboratory personnel on (1) the requirements and expectations of animal users, (2) two relevant AALAS Learning Library training modules and (3) a hands-on anesthetic course. Approval of new protocols were also withheld until all required training and counseling of the PI with the Attending Veterinarian on protocol compliance have been completed.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4712



June 22, 2018

Axel Wolff M.S., D.V.M.
Director, Division of Compliance Oversight Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda MD 20892-7982

Dear Dr. Wolff,

Re: Final Incident Report
OLAW Assured Facility Number D16-00258 (A3448-01)

This is a final report on an incident at Uniformed Services University of the Health Sciences (USU) (OLAW Assured Facility Number D16-00258/A3448-01) that was initially reported to the Office of Laboratory Animal Welfare (OLAW) on 9 April 2018.

On the morning of 7 March 2018, a USU Laboratory for Animal Medicine (LAM) animal husbandry technician found a cage of mice that had recently been transferred from a breeding protocol. There were four mice in the cage; 3 of the 4 were dead, the 4th was moribund, and their bodies were lined up in parallel. The attending veterinarian (AV) euthanized the moribund mouse and immediately addressed the incident with the Principal Investigator. Through follow-on discussions between the AV and the PI, it was determined that one of the PI's staff members had injected the 4 mice on 6 March 2018 with 200 microliters of tribromoethanol (Avertin®) IP in order to "test the newly diluted batch". The staff member had injected the mice at 1700 and failed to monitor the animals (after confirming that they had lost righting reflexes) until the next morning. The PI reported the incident to the Institutional Animal Care and Use Committee (IACUC) on 12 March, and further studies under the protocol were discontinued.

A review of the protocol revealed three issues relating to this incident that constituted deviations from the approved protocol:

- 1) The use of tribromoethanol or any other anesthetic was not mentioned in the approved protocol, and therefore not approved.
- 2) There was nothing in the approved protocol that authorized the laboratory staff to "test" the concentration of an anesthetic by injecting it into their research mice.
- 3) USU Standard Operating Procedures require that anesthetized animals be continuously monitored from administration of the anesthetic until return to ambulatory status. Clearly, monitoring was not provided in this incident.

Learning to Care for Those in Harm's Way

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

This protocol expired on 29 March 2018, and no further studies were conducted under that protocol. The incident was initially discussed at the 17 April meeting of the IACUC.

There was unanimous agreement that the PI and all persons in his lab listed on the protocol should be retrained on the requirements for and expectations of persons using animals for research or education at USU. The committee indicated a new protocol would not be approved until the PI and all persons on the protocol had completed the required re-training and had met to discuss the incident and appropriate procedures with the AV to discuss the incident. The PI was notified that it was the responsibilities of the PI and all laboratory staff to be fully conversant with the procedures approved in an IACUC protocol, and to conduct these procedures in an approved manner. The PI and staff were also required be retrained in a hands-on anesthesia course with a veterinarian, and to complete two on-line training courses from the AALAS Learning Library: "Working with the Mouse" and "Common Compliance Issues".

The PI and all Lab Staff have now presented to the IACUC Office certificates of successful completion of the required on-line training courses, and the AV has confirmed to the IACUC that all required re-training has been completed.

The IACUC has reviewed the new protocol submission from the PI, and this has now been approved.

The IACUC considers this incident closed.

Sincerely,

(b) (6)

Yvonne T. Maddox Ph.D.
Vice President for Research
Institutional Official
Uniformed Services University

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, June 27, 2018 7:42 AM
To: (b) (6)
Subject: RE: USU Final Incident Report_OLAW Assured Facility Number D16-00258

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

From: (b) (6)
Sent: Friday, June 22, 2018 5:54 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6) Yvonne Maddox <Yvonne.maddox@usuhs.edu>; (b) (6)
Subject: USU Final Incident Report_OLAW Assured Facility Number D16-00258

Dear Dr. Wolff,

On behalf of Dr. Yvonne T. Maddox, USU Vice President for Research, and Institutional Official, I have attached the final incident report as referenced above.

Thank you.

Best, (b) (6)



To Brent Morse, DVM, DACLAM, OLAW

Dr. Morse,

This is an initial report of an incident relating to the research animal care and use program at Uniformed Services University, Bethesda MD. On the morning of 7 March 2018, a LAM animal husbandry technician found a cage of mice (b) (4) that had recently been transferred from a breeding protocol. There were four mice in the cage; 3 of the 4 were dead, the 4th was moribund, and their bodies were lined up in parallel. The AV euthanized the moribund mouse and immediately addressed the incident with the Principal Investigator. Through follow-on discussions between the AV and the PI, it was determined that one of the PI's staff members had injected the 4 mice 6 March 2018 with 200 microliters of tribromoethanol (Avertin®) IP in order to "test the newly diluted batch". The staff member had injected the mice at 1700 and failed to monitor the animals after confirming that they had lost righting reflexes. The PI reported the incident to the IACUC on 12 March, and further studies under the protocol were discontinued.

A review of the protocol revealed three issues relating to this incident that constitute deviation from the approved protocol:

- 1) The use of neither tribromoethanol or any other anesthetic is described in the approved protocol.
- 2) There is nothing in the approved protocol that authorizes the laboratory staff to test the concentration of an anesthetic by injecting it into their research mice.
- 3) USU Standard Operating Procedures require that anesthetized animals be continuously monitored from administration of the anesthetic until return to ambulatory status. Clearly monitoring was not provided in this incident.

This protocol expired on 29th March 2018 and no further studies have been conducted. The IACUC will discuss the incident and appropriate actions including re-training of laboratory personnel at its scheduled meeting in April. A renewal request for this protocol has been submitted to the IACUC; this will not be approved until this incident is resolved.

A final report on the incident will be sent to OLAW when the incident has been resolved. Please contact us if you have any questions or concerns.

Contact person making report:

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, April 10, 2018 8:29 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: USARMY Ft Detrick MEDCOM USAMRMC Other ACURO; (b) (6)
(b) (6) Brian Cox; (b) (6)
Subject: RE: Reportable Event - Preliminary Report - USUHS

Thank you for sending this preliminary report (b) (6) We will open a case file and await the final report.

Regards, Brent Morse

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

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From: (b) (6)
Sent: Tuesday, April 10, 2018 8:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: USARMY Ft Detrick MEDCOM USAMRMC Other ACURO <usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil>;
(b) (6) Brian Cox <brian.cox@usuhs.edu>;
(b) (6) Yvonne Maddox
<yvonne.maddox@usuhs.edu>
Subject: Reportable Event - Preliminary Report - USUHS

Dear Dr. Morse,

Attached is an initial incident report regarding a deviation from a protocol that occurred at Uniformed Services University. A final report will be submitted once the investigation has concluded.

Please let me know if you have any questions or concerns.

Thank you,

(b) (6)

(b) (6)