



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 10, 2020

Re: Animal Welfare Assurance
A3448-01 [OLAW Case 1F]

Bruce Doll, DDS, Ph.D., MBA
Assistant Vice President for Technology
Research and Innovation
IACUC Institutional Official
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814

Dear Dr. Doll,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 4 September 2020 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Uniformed Services University of the Health Sciences. Your letter supplements information provided in the initial email report received on March 19, 2020. According to the information provided, OLAW understands that on March 12, 2020 a PI encountered a problem with an anesthesia unit resulting in four mice which did not recover from anesthesia. The unit was reset by a facility staff member and anesthesia of the remaining mice was uneventful. It was noted that this activity was PHS - funded.

To prevent another incident, the IACUC implemented the following measures:

- 1) The flow rate and proper functioning of the anesthesia equipment was verified.
- 2) The PI and research staff attended a retraining on the anesthesia machine.
- 3) A team of IACUC members completed a post approval monitoring of the anesthesia and irradiation procedures and reported that everything went according to protocol with no unexpected or adverse events.

OLAW believes that the preventive measures put in place by the Uniformed Services University of the Health Sciences are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. OLAW appreciates being informed of this issue and finds no cause for further action.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2020.09.11 07:58:22 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3448-1F



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

OFFICE OF THE VICE PRESIDENT FOR RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799
www.usuhs.edu



04 September 2020

Brent Morse, DVM, DACLAM
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. Morse,

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 19 March 2020.

The PI for protocol AFR-19-001, self-reported an unexpected event that occurred with their NIH funded protocol on 12 March 2020. The IACUC was informed on 13 March 2020.

On 12 March, the PI encountered a problem with the anesthesia unit. This was an irradiation experiment with multiple runs which each accommodate 8 mice per run. In the first run of 8 mice, 4 remained under anesthesia whereas 4 would arouse continually during anesthesia. After increasing the isoflurane flow, the mice remained anesthetized for the duration of the radiation. At the end of the irradiation, all 8 mice appeared in good health when transferred to the pre-warmed recovery cages. However, 4 mice did not wake within the expected time of recovery and were examined carefully for signs of life. After the external examination, they were pronounced dead. Cervical dislocation was carried out to confirm death and the carcasses were disposed of. The animals did not appear to experience pain as they were under anesthesia and there were no physical signs of distress or pain.

Before any further radiations were initiated, experiment staff reached out to a facility staff member and after resetting the anesthesia unit, irradiation of 96 more mice was successful without any unexpected events.

A subcommittee was appointed and an investigation occurred.

The IACUC made the following recommendations:

1. Check the flow rate and functioning of anesthesia unit.
2. Train PI and staff on the anesthesia machine.
3. Have IACUC members conduct a post approval monitoring of the procedure.

The PI agreed to all recommendations put forth by the IACUC. The flow rate and proper functioning of the anesthesia equipment was verified. The PI and research staff attended a re-training on the anesthesia machine. A team of IACUC members completed a post approval monitoring of the anesthesia and irradiation procedures and reported that everything went according to protocol with no unexpected or adverse events.

The IACUC now considers this incident closed.

Sincerely,

DOLL.BRUCE.ALF
RED.1005726154

Digitally signed by
DOLL.BRUCE.ALFRED.1005726154
Date: 2020.09.04 15:45:18 -04'00'

Bruce Doll, DDS, Ph.D., MBA
Assistant Vice President for Technology Research and Innovation
IACUC Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 9, 2020 8:02 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report USUHS D16-00258 (A3448-01) March 2020

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: IACUC <iacuc@usuhs.edu>
Sent: Tuesday, September 8, 2020 11:23 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil; dha.ncr.reg-support.mbx.r2o2@mail.mil; accredit@aaalac.org
Cc: iacuc@usuhs.edu; Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>; Bruce Doll <bruce.doll@usuhs.edu>; (b) (6)
(b) (6)
(b) (6)
Subject: Final Report USUHS D16-00258 (A3448-01) March 2020

IACUC@USUHS.EDU appears similar to someone who previously sent you email, but may not be that person. [Learn why this could be a risk](#) [Feedback](#)

Dear Dr. Morse,

Please see the attached final report regarding the unexpected event that occurred on March 12, 2020 at the Uniformed Services University of the Health Sciences.

If you require any further information, feel free to contact me. Thank you,

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(b) (6)

Wolff, Axel (NIH/OD) [E]

A3448-1F

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 19, 2020 12:40 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Unexpected Event - March 2020 - USUHS D16-00285

Thank you for this report, (b) (6) We will open a new case file.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, March 19, 2020 12:29 PM
To: usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; DHA NCR Reg Support Mailbox R2O2 <dha.ncr.reg-support.mbx.r2o2@mail.mil>; accredit@aaalac.org
Cc: (b) (6)
(b) (6)
Subject: Unexpected Event - March 2020 - USUHS D16-00285

Dear Dr. Wolff,

Please find the attached preliminary report regarding a mouse protocol at the Uniformed Services University. A final report will be submitted by the IO once the investigation has concluded.

Thank you for your review.

(b) (6)

The PI for protocol AFR-19-001, self-reported an unexpected event that occurred with their NIH funded protocol on 12 March 2020. The IACUC was informed on 13 March 2020.

On 12 March, the PI encountered trouble with the anesthesia unit. In the first run of 8 mice, 4 stayed under whereas 4 kept waking. After increasing the isoflurane, the mice stayed under. At the end of the irradiation, all 8 mice appeared OK when transferred to the pre-warmed recovery cages. However, 4 mice did not wake and were pronounced dead. Cervical dislocation was carried out before disposing off the carcasses. The animals did not undergo pain as they were under anesthesia.

Staff reached out to a facility staff member and after resetting the anesthesia unit, irradiation of 96 more mice was successful.

The IACUC formed a sub-committee for an investigation.