



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 2, 2021

Re: Animal Welfare Assurance
#A3226-01 (OLAW Case 2Q)

Dr. Elizabeth Boyd
VP for Research Administration
Fred Hutchinson Cancer Research Center
1101 Fairview Avenue North
Seattle, WA 98109-1024

Dear Dr. Boyd,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated February 12, 2021 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Fred Hutchinson Cancer Research Center. Your letter supplements the information in the prompt telephone preliminary report on January 14, 2021. According to the information provided, OLAW understands that on January 12, 2021, five mice died during isoflurane anesthesia induction using a new anesthesia machine. Comparative Medicine staff determined the air intake valve cap had not been removed and the mice likely died of asphyxiation due to the machine's small chamber size and active exhaust system. This exhaust system, combined with the lack of air intake, created a vacuum, and resulted in nearly immediate hypoxia and death. The associated activity was not PHS funded.

Following are the corrective and preventive actions:

1. Use of the new anesthesia machine has ceased until corrective actions have been completed.
2. The air intake valve cap has been removed.
3. Comparative Medicine staff will develop a training course, signage, and SOP for the new anesthesia machine, along with other anesthesia machines.
4. All new equipment will be tested using live animals before becoming available to researchers.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by the Fred Hutchinson Cancer Research Center to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S
Date: 2021.03.02 13:36:41 -05'00'

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

cc: IACUC Contact



FRED HUTCH
Institutional Review Office

Elizabeth Boyd, PhD
Vice President for Research Administration and Faculty Affairs
1100 Fairview Ave. N.
Seattle, WA 98109-1024
Tel [REDACTED] (b) (6)
eboyd@fredhutch.org

February 12, 2021

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Reportable Event

Animal Welfare Assurance Number:
Name of Institution:

D16-00142 (Legacy #A3226-01)
Fred Hutchinson Cancer Research Center
No PHS funding for this project

Dear Dr. Morse:

This letter serves as follow-up to an initial verbal notification made by Meghan Scott, Director of the Institutional Review Office, on January 14, 2021, regarding a reportable event.

A Concern/Reportable Event was submitted to the Institutional Review Office by a Fred Hutch Comparative Medicine veterinarian on January 13, 2021. The Concern described an event, occurring on January 12, 2021, in which five mice died during isoflurane anesthesia induction using a SomnoSuite Low Flow anesthesia machine.

The research team performing anesthesia contacted Comparative Medicine during the procedure to report that the anesthesia machine was sounding an alarm and later reported that the entire cage of mice (5 total) died in the induction chamber in less than one minute. Upon examining the anesthesia machine, Comparative Medicine staff determined the air intake valve cap had not been removed and the mice likely died of asphyxiation, rather than isoflurane overdose. In addition to the blocked air intake, contributing factors included the machine's small chamber size and active exhaust system. This exhaust system, combined with the lack of air intake, would have created a vacuum and resulted in nearly immediate hypoxia and death.

The SomnoSuite Low Flow anesthesia machine is new to the Fred Hutch facility and most research staff. Comparative Medicine staff performed trial runs and prepared operating instructions based on the manufacturer's manual; however, no live mice were anesthetized during the trial runs.

The IACUC reviewed the event at the fully convened IACUC meeting on February 2, 2021, and Comparative Medicine staff proposed the following corrective action plan:

- 1) The air intake valve cap, which is intended to be removed prior to use, has now been removed, and all use of the SomnoSuite Low Flow anesthesia machine has ceased until the following action has been completed.
- 2) Comparative Medicine staff will develop a training course for the SomnoSuite Low Flow anesthesia machine, along with other anesthesia machines in the facility, and will require that researchers complete training prior to use. In addition to a training course, Comparative Medicine staff will write a detailed, step-by-step standard operating procedure (SOP) for all users.
- 3) Signage will be posted to indicate the following:
 - a. Training must be completed prior to use.
 - b. In the event of an alarm, halt the procedure immediately, remove animals from the induction chamber, and contact Comparative Medicine staff.
 - c. Do not load more than 2 mice into the induction chamber at one time.
 - d. Do not occlude the air intake valve.
- 4) An amendment to Comparative Medicine IACUC protocol "1526: Sentinel Rodent Disease Surveillance and Comp Med Teaching Labs" was submitted and reviewed at the meeting of February 2, 2021. This amendment will allow Comparative Medicine staff to perform quality assurance and safety testing on new equipment, such as anesthesia machines, using live animals. All new equipment will be tested using live animals before becoming available to researchers.

The IACUC determined the corrective action plan was adequate and no additional action was required. The IACUC acknowledged that while the event involved animals on a research protocol, the Comparative Medicine department is responsible for all corrective actions. The Principal Investigator of the research protocol was informed of the incident.

If you have any suggestions for further improvements to our program, please do not hesitate to share them with us. Thank you for your time in reviewing this correspondence. If I can be of any further assistance, please contact me at (b) (6)

Sincerely,

Elizabeth
Boyd, PhD

Digitally signed by
Elizabeth Boyd, PhD
Date: 2021.02.17 15:33:23
-08'00'

Elizabeth Boyd, PhD
Vice President for Research Administration and Faculty Affairs
Fred Hutchinson Cancer Research Center

cc: Meghan Scott, Director, Institutional Review Office
Bruce Busby, CHP, MS, Acting IACUC Chair
Gordon Roble, DVM, Attending Veterinarian
VP, General Counsel

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 26, 2021 7:20 AM
To: Scott, Meghan K
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW reporting letter_ D16-00142-Legacy #A3226-01-Fred Hutchinson Research Center

Thank you for this report, Ms. Scott. We will send a response soon.

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

From: Scott, Meghan K <mscott@fredhutch.org>
Sent: Wednesday, February 24, 2021 12:33 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Scott, Meghan K <mscott@fredhutch.org>
Subject: OLAW reporting letter_ D16-00142-Legacy #A3226-01-Fred Hutchinson Research Center

Dear Dr. Morse:

Attached please find the final report as follow-up to an initial verbal notification that was provided on January 14, 2021 regarding a reportable event.

If you have any questions, please contact me. We would appreciate a confirmation via email that you have received the attached document.

Meghan Scott
Director
Institutional Review Office
O (b) (6)
mscott@fredhutch.org



Fred Hutchinson Cancer Research Center
1100 Fairview Ave. N., Mail Stop J2-100
Seattle, WA 98109
fredhutch.org

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Initial Report of Noncompliance

By: BCM

Date: 1/14/2021

Time: 1:06

Name of Person reporting: Megan Scott

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Fred Hutchinson Cancer Rsch Cen

Assurance number: A3226

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened?

Valve on new anesthesia machine not prepared properly to put into service. Cage of 5 mice were asphyxiated.

Species involved: mus musculus

Personnel involved: Researcher

Dates and times: ?

Animal deaths: yes

Projected plan and schedule for correction/prevention (if known):

Machine taken out of service. IACUC to be notified soon.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case #