



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) 402-7065

November 21, 2019

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

Dr. Gary Gilliland
President and Director
Fred Hutchinson Cancer Research Center
1101 Fairview Avenue North
Seattle, WA 98109-1024

Dear Dr. Gilliland,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated November 5, 2019 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Fred Hutchinson Cancer Research Center. This letter had been preceded by a preliminary report to OLAW on July 7, 2019.

According to the information provided, our office understands that a student failed to replace a feeding rack on a cage of mice on June 24, 2019. The cage held one adult female and four pups. On Friday, June 28, 2019, a Comparative Medicine staff member found the cage. The pups were no longer in the cage and the dam appeared lethargic and was later euthanized despite supportive care. These animals were not part of a PHS-funded study.

Corrective actions consisted of the Principal Investigator counseling the student directly and then speaking to all laboratory members about diligence when working with animals and ensuring proper care.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals are commendable and avoid the perception of a double standard. We appreciate having been informed of this matter and at this time find no cause for further action by this office.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Animal Welfare Policy Specialist
Office of Laboratory Animal Welfare

cc: IACUC Contact
Director, Institutional Review Office



FRED HUTCH
Institutional Review Office

D. Gary Gilliland, MD, PhD
President and Director
PO Box 19024; D1-060
Seattle, WA 98109-1024
Tel: (b) (6)
Email: gary@fredhutch.org

November 5, 2019

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Report of Protocol Noncompliance

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 Karen Hansen, Director of the Institutional Review office (IRO), on July 7, 2019 regarding a reportable event.

On August 6, 2019, the Fred Hutchinson Cancer Research Center (Fred Hutch) Institutional Animal Care and Use Committee (IACUC), reviewed a Reportable Event Form dated July 4, 2019.

The Principal Investigator self-reported an incident related to an animal research protocol. The report described an event where on Friday, June 28, 2019, a Comparative Medicine (CM) staff member identified a breeder cage that did not contain the wire bar for holding food. After review, it was determined that on Monday, June 24, 2019, a research student was working with a cage of mice and transferred a litter of four pups from one dam to a different dam (as described and approved in the IACUC protocol). However, the research student forgot to replace the wire feeder and returned the cage to the cage housing rack. When the CM staff member discovered the mistake, the fostered rodent pups were no longer in the cage and the dam was found to be lethargic. Supportive food and diet recovery gel were immediately provided to the mouse. The dam was euthanized on July 3, 2019.

The corrective action involved the Principal Investigator speaking with the research student directly and then speaking to all members of the laboratory regarding extreme and diligence when working with animals. The Principal Investigator reiterated that staff should take their time to ensure that all cages have adequate food and water after handling a cage.

The IACUC reviewed the corrective action plan and determined the corrective measures that had been taken were adequate. The IACUC further noted that the Principal Investigator conveyed clear understanding of the seriousness of the situation and stressed the importance to research staff of taking proper time to do careful work, to minimize unnecessary mistakes. The IACUC determined that no further action was required.

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,

(b) (6)

D. Gary Gilliland, MD, PhD
President and Director
Fred Hutchinson Cancer Research Center

cc: Karen Hansen, Director, Institutional Review Office
George Georges, MD, IACUC Chair
Rajesh Uthamanthil, DVM, Attending Veterinarian
(b) (6)
VP, General Counsel

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 18, 2019 6:39 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Reporting Letter_D16-00142-legacy #A3226-01 Fred Hutchinson Cancer Research Center

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

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

From: (b) (6)
Sent: Saturday, November 16, 2019 2:29 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: OLAW Reporting Letter_D16-00142-legacy #A3226-01 Fred Hutchinson Cancer Research Center

Dear Dr. Morse:

Attached please find the final report as follow-up to an initial verbal notification made by Karen Hansen on July 9, 2019 regarding a reportable event. We apologize for the delay in submitting the final report. We had a staff member unexpectedly need to take Family Medical Leave for several weeks, which resulted in the delay of final reporting.

If you have any questions please feel free to contact me.

We would appreciate a confirmation via email that you have received the attached document.

Sincerely,

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



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

This electronic message transmission contains information which may be privileged or confidential. The information is intended for the use of the recipient named above. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, any distribution or copying of this communication or use of the information it contains is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone, return the original message to us and delete this message.



Initial Report of Noncompliance

By: *sgm*Date: *7/9/19*Time: *Voicemail*Name of Person reporting: *Karen Hansen*Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: *Fred Hutchinson Cancer Resch. Cen.*Assurance number: *A3226*Did incident involve PHS funded activity? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *Student moved newborn pups into cage with different female. Did not replace feeder on cage. Female cannibalized pups.*Species involved: *Mouse*Personnel involved: *Student*Dates and times: *6/24/19*

Animal deaths:

Supportive care given to ♀

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____