



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

August 12, 2019

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

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 August 1, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Fred Hutchinson Cancer Research Center, following up on an initial telephone report on June 26, 2019. According to the information provided, OLAW understands that a dog was euthanized with expired euthanasia solution. There were no problems with the procedure due to using the outdated drug.

The corrective actions consisted of discarding the expired drug and counseling the animal care staff on using only in-date drugs.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Director, Institutional Review Office

A3226-



FRED HUTCH
Institutional Review Office

D. Gary Gilliland, MD, PhD
President and Director
PO Box 19024; D1-060
Seattle, WA 98109-1024
Tel: 206-667-6600
Email: gary@fredhutch.org

August 1, 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: 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 Karen Hansen, Director of the Institutional Review office (IRO), on June 26, 2019 regarding a reportable event.

A reportable event form dated June 12, 2019 was submitted to the Fred Hutch IRO. The above-mentioned event involved the discovery that a single dog was euthanized on June 5, 2019 with expired Euthasol (the bottle having expired five days prior on May 31, 2019). It was determined that a Comparative Medicine (CM) staff member had discarded all unopened bottles of Euthasol from the shelf in the month of May during the monthly expired drug check process. However, it appears that because this bottle of Euthasol was already opened, it was overlooked during the process of discarding the other bottles prior to the expiration date. There were no complications during the euthanasia and no increased pain or distress was involved.

The corrective actions consisted of discarding the expired Euthasol bottle. The veterinarian and supervisor met with the CM staff members responsible for maintaining the drug lockbox and performing expired drug checks. The CM staff members were reminded of the expectations for ensuring drugs are within date and of the importance of checking all bottles (both opened and unopened) at the time of use and at monthly expiration checks.

At the convened meeting on July 2, 2019, the IACUC determined that adequate corrective

action measures have been taken and that no further action is required at this time. The IACUC members also noted that while use of expired drugs is not allowed, that literature has demonstrated the stability of long-expired medications and that pentobarbital (the active ingredient in Euthasol), appears to maintain greater than 90% potency at even 28-40 years past expiration (<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1377417>). The known long-term stability of this drug supports that the 5 days elapsed time from expiration did not compromise the efficacy of the drug.

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

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 5, 2019 9:42 AM
To: (b) (6)
Subject: RE: OLAW Reporting Letter - D16-00142-legacy #A3226-01 Fred Hutchinson Cancer Research Center

Thank you for your response letter. Dr. Morse will respond soon.

Regards,
Joan

From: (b) (6)
Sent: Sunday, August 4, 2019 3:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Hansen, Karen M <khansen@fredhutch.org>
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 June 26, 2019 regarding a reportable event.

If you have any questions please contact:

Karen Hansen
Director, Institutional Review Office
Fred Hutchinson Cancer Research Center
Phone: (b) (6)
Email: khansen@fredhutch.org

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

Sincerely,

(b) (6)



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: OLW

Date: 6/26/19

Time: PM

Name of Person reporting: Karen Hansen

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Fred Hutchinson Cancer Ctr

Assurance number: A3226

Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Exposed euthanasia drug used. No problems with animals

Species involved: ?

Personnel involved:

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____