



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

July 26, 2022

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

Dr. Frederick Applebaum
Executive VP and Deputy Director
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North
Seattle, WA 98109

Dear Dr. Applebaum,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated July 19, 2022 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 April 8, 2022. According to the information provided, OLAW understands that on April 7, 2022, your institution was notified of an event in which 46 mice received irradiated, commercially available, high-fat chow for three weeks that was found to be expired. Upon realization that the feed was expired, it was immediately discarded and replaced with standard mouse chow, and a new supply of high-fat chow was ordered. The project was not PHS funded.

Corrective and preventive actions: Comparative Medicine (CM) staff met with the research team to discuss policies and standard practices regarding the use and storage of specialty feeds. Going forward, specialty diets received by the lab will be transferred to CM for appropriate storage based on manufacturer specifications and tracking of expiration dates.

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 expectations 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: 2022.07.26 13:06:50 -04'00'

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

cc: IACUC contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Tuesday, July 26, 2022 1:52 PM
To: fappelba@fredhutch.org
Cc: OLAW Division of Compliance Oversight (NIH/OD); houghton@fredhutch.org;
(b) (6)
Subject: OLAW Cases A3226-2Z and A3226-3A
Attachments: A3226-2Z.pdf; A3226-3A.pdf

Good afternoon Dr. Appelbaum,

Attached please find Dr. Morse's final responses to OLAW Cases A3226-2Z and A3226-3A. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

A3226-27



FRED HUTCH
Institutional Review Office

July 19, 2022

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 (CON00000071)

Animal Welfare Assurance Number:	D16-00142 (Legacy #A3226-01)
Name of Institution:	Fred Hutchinson Cancer Center
PHS Funding:	No PHS Funding for this project

Dear Dr. Morse:

This letter serves as follow-up to an initial verbal notification made by (b) (6) on April 8, 2022, regarding a reportable event.

On May 3, 2022, the Fred Hutchinson Cancer Center (Fred Hutch) Institutional Animal Care and Use Committee (IACUC) initially reviewed a reportable event submitted on April 7, 2022. The report described an event in which 46 mice received irradiated, commercially available, high-fat chow for three weeks that was found to be expired. The feed had been received, aliquoted and stored frozen by the research team. Upon realization that the feed was expired, it was immediately discarded and replaced with standard mouse chow, and a new supply of high-fat chow was ordered. CM staff met with the research team to discuss policies and standard practices regarding the use and storage of specialty feeds. Going forward, specialty diets received by the lab will be transferred to CM for appropriate storage based on manufacturer specifications and tracking of expiration dates.

Mice receiving the feed displayed a greasy, unkempt haircoat and increased body weight as expected from a high-fat diet. The IACUC asked for additional information about the health status of the animals, and the event was re-reviewed at the June 7, 2022 convened meeting after receiving clarifications from the Principal Investigator. The IACUC could not definitively determine whether the expired feed did or did not contribute to any adverse outcomes; however, the IACUC did recommend refinement of the glucose tolerance testing procedure approved on the protocol for one cohort of animals. A protocol amendment was submitted by the research team and reviewed concurrently at the June 7 IACUC meeting.

The IACUC determined the corrective and preventive action plan was adequate, and no further action was required. The protocol amendment was approved by the IACUC on July 19, 2022.

If you have any suggestions for further improvements to our program, please do not hesitate to share them with us. If I can be of any further assistance, please contact me at (b) (6) or fappelba@fredhutch.org.

Sincerely,

(b) (6)

Fred Appelbaum, MD
Executive Vice President & Deputy Director
Fred Hutchinson Cancer Center

cc:

(b) (6)

A McGarry Houghton, IACUC Chair
Gordon Roble, DVM, Attending Veterinarian
Principal Investigator

McCoy, Devora (NIH/OD) [E]

From: (b) (6)
Sent: Friday, July 22, 2022 1:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: [EXTERNAL] OLAW reporting letter_ D16-00142-Legacy #A3226-01-Fred Hutchinson Cancer Center (Concern 71)
Attachments: 22.07.19 Concern 71_OLAW_final.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Morse:

Attached please find the final report as follow-up to an initial verbal notification provided on April 8, 2022 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.

Best,

(b) (6)



CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 22, 2022 2:13 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW reporting letter_ D16-00142-Legacy #A3226-01-Fred Hutchinson Cancer Center (Concern 71)

Good afternoon (b) (6)

Thank you for sending this final report. We will review it and send a response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Friday, July 22, 2022 1:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] OLAW reporting letter_ D16-00142-Legacy #A3226-01-Fred Hutchinson Cancer Center (Concern 71)

Dear Dr. Morse:

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Best,

(b) (6)

(b) (6)

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A3226-2Z

Initial Report of Noncompliance

By: BCM

Date: 4/8/2022

Time: voicemail

Name of Person reporting: (b) (6)
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: Fred Hutchinson Cancer Rsch Cen
Assurance number: A3226

Did incident involve PHS funded activity? no
Funding component:
Was funding component contacted (if necessary):

What happened?

Mice had been fed expired experimental diet for 2-3 weeks. Nutritional status unknown since diet had been expired for about 18 months.

Species involved: mus musculus
Personnel involved: Researcher
Dates and times: ?
Animal deaths:

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

IACUC investigating. Mice placed on regular diet while awaiting replacement experimental feed.

Projected submission to OLAW of final report from Institutional Official:

< 60 days (after May IACUC meeting)

OFFICE USE ONLY

Case #