



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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

February 3, 2021

Re: Animal Welfare Assurance
A3143-01 [OLAW Case 1D]

Dr. Candace Johnson
President and CEO
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14263

Dear Dr. Johnson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 17, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Roswell Park Cancer Center. According to the information provided, OLAW understands that on July 18th, the Attending Veterinarian identified a moribund mouse and directed a staff member to euthanize the animal however the animal was found dead the next morning on July 19, 2020. Additionally, OLAW understands that one bottle of expired buprenorphine was used three times on mice between March 9-18, 2020 and a second bottle of expired buprenorphine was used eight times on mice between June 22- August 17, 2020. Upon review, no apparent health issues were observed in mice that has undergone surgical procedures with expired buprenorphine. The studies were not funded by PHS.

As a corrective measure, the IACUC requested a corrective and preventative plan of action (CAPA) to prevent recurrence of both reported incidents. The CAPA includes retraining laboratory personnel to ensure timely response to animal health concerns and monitoring drug expiration dates, updating cage cards with proper contact information to limit delays in response, ensuring that all responsible personnel have been advised to request assistance from Veterinary Services and new signage added to lock boxes displaying expiration dates and reminders to dispose/replenish stock as needed.

OLAW appreciates the prompt consideration of this matter by the Roswell Park Cancer Center which is consistent with the philosophy of institutional self-regulation. 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. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,
Nicole L.
Lukovsky-
akhsanov -S

Digitally signed by Nicole
L. Lukovsky-akhsanov -S
Date: 2021.02.03 11:07:12
-05'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3143-1D



Michael T. Moser, Ph.D.
Chair Institutional Animal Care and Use Committee (IACUC)
A457 Carlton House
Buffalo, NY 14263
Phone: 716 845-1155
FAX: 716 845-1258
michael.moser@roswellpark.org

(b) (6)

To: Candace Johnson, Ph.D., RPCI Institute Official, President and CEO
From: Michael T. Moser, Ph.D., Chair RPCI IACUC
DATE: November 17, 2020
Re: Animal Welfare Concern: Use of Expired Analgesics and Response Time for a Moribund Mouse

This is to report non-compliance animal welfare incidents that happened to mice enrolled on protocol 1321M. During the IACUC random review of LASR (Laboratory Animal Shared Resource) Daily Bed Check Spreadsheet during the September 15, 2020 meeting of the full committee Dr. T's protocol 1321M, along with 6 other protocols, was selected for review. During the review of the July 2020 LASR Daily Bed Check spreadsheet there was a concern raised by the IACUC for a mouse found dead on July 19, 2020 that had been flagged for a moribund condition on July 18th. Dr. Sandra Sexton, LASR Attending Veterinarian had contacted Ms. T at 1:32 pm on July 18th via e-mail asking that the mouse be euthanized because it "was very moribund and could not ambulate and would likely die overnight". Ms. T replied via e-mail at 2:45 pm on July 18th "thanks will do". The mouse was found dead the morning of July 19, 2020. The IACUC feels this was not a timely response to an animal health concern and caused unnecessary pain and distress to the mouse.

Another concern discussed by the committee was the use of expired buprenorphine. On review of Veterinary Services controlled drug reports it was observed that expired buprenorphine had been administered to mice. The first identification of expired buprenorphine use was noted on the controlled drug report B1213 which had an expiration date of March 6, 2020 and was used 3 times on mice between March 9-18. The other drug report B1244 which had an expiration date of June 14, 2020 and was used 8 times on mice between June 22 – August 17, 2020. Upon review, there had been no apparent health issues observed in mice that had undergone surgical procedures with the expired buprenorphine. Although there did not appear to be any animal welfare concerns resulting from the use of the expired buprenorphine, the IACUC believes this repeated use of expired buprenorphine are reportable events.

IACUC sent a memo to (b) (6) on September 28, 2020 expressing concern regarding (b) (6) failure to euthanize the distressed mouse in a timely manner and the use of expired buprenorphine. The IACUC requested a corrective and preventative plan of action (CAPA) to prevent recurrence of a failure to respond in a timely manner to a health concern and the use of expired buprenorphine. The CAPA was received from (b) (6) on October 16, 2020. The CAPA stated the following:

"This Corrective and Preventative action (CAPA) plan is in regard to the "flagging of cages under protocol 1321M; found dead, and expired Buprenorphine" memo received on September 28, 2020. As always, we take these issues very seriously and do our best to eliminate any potential issues before they arise. In regards to responding in a timely manner, all laboratory personnel will be retrained on making a timely response to any and all animal health concern. To aid us in this retraining, we seek guidance from the committee on what is "a timely manner", as PIs are often involved in multiple studies. If in the middle of one study, they may not be able to leave as soon as they would like to deal with the flagged cages. Better understanding of these timelines will help them determine whether they should get DLAR staff involved not.

In addition to retraining on timely response, cage cards will be updated with the proper contact name and number. (b) (6) promptly forwards flags to study PIs, but there is often a lag, and that lag results in delays. Updated cage cards will ensure that the proper study PI is contacted directly, and thereby eliminating (b) (6) as the middle person. If a health concern cannot be taken care of in a timely matter, all responsible persons have been advised to request assistance from Veterinary Services to euthanize the mouse."

"In regard to the expired Buprenorphine usage, all laboratory personnel have been retrained on monitoring the expiration date of all drugs used in animal studies. New signage has been added to our lock box that will display the current expiration date of the buprenorphine being actively used for animal studies. The additional signage will serve as a reminder to dispose of and replenish buprenorphine stocks prior to expiration. After a new batch of buprenorphine is received, the signage will be updated to reflect the new date. We anticipate this will prevent future lapses in drug usage after expiration."

The IACUC committee discussed (b) (6) CAPA at the November meeting (11/03/2020) and feels that (b) (6) CAPA addresses sufficiently the root causes, the corrective plan needed and the preventative processes to prevent a recurrence of these non-compliances. The IACUC has contacted (b) (6) regarding the request for IACUC's guidance as to timely response and has requested that he contact a LASR Veterinarian to discuss specifics of an appropriate timely response because appropriate response times are dependent on the specific animal welfare concern by Veterinary Services. Department of Defense (DoD) award funds were used for the studies that the mice involved in these incidents were enrolled.

The IACUC believes the delay in euthanizing the mouse that was in a moribund condition did cause the mouse unnecessary pain and distress and therefore may be reportable. The IACUC also believes the use of expired buprenorphine, although the animals exhibited no signs of distress, may also be reportable. If you have any additional questions, require clarification or further action by the IACUC at this time, please feel free to contact me.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 30, 2020 8:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident report Roswell Park

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

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

From: (b) (6)
Sent: Friday, November 27, 2020 11:54 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Johnson, Candace <Candace.Johnson@RoswellPark.org>
Subject: Incident report Roswell Park

OPRR Assurance D16-00087 (#A3143-01).

Dear Dr. Morse,

Please accept the enclosed report as required by 9 CFR 2.31 (c) (3) and (d) (7) Subchapter A of the Animal Welfare Act, as well as PHS Policy IV.F.3.

Corrective action has been instituted as per the attached document. Roswell Park Cancer Institute is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions, please do not hesitate to contact me at 716-845-5772.

Thank you in advance for your cooperation in this matter.

Sincerely,
Candace S. Johnson, Ph.D.
President and CEO

(b) (6)



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