



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

January 13, 2020

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

Dr. Camille P. Wicher
Vice President, Corp. Ethics and
Research Subject Protection
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14263

Dear Dr. Wicher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 3, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Roswell Park Cancer Institute. According to the information provided, a mouse was found in distress with a distended abdomen due to ascites, the investigator was notified but did not euthanize the mouse in a timely fashion, and the animal died later that day. The investigator also failed to adequately monitor mice with tumors as stated in the protocol and did not conduct ongoing body scoring. Mice that did not have a recent body score needed to be euthanized due to abdominal distension.

The corrective actions consisted of having the investigator undertake online retraining; having a senior laboratory member supervise the investigator; having a co-worker monitor and score mice when the investigator is unavailable; having the investigator certify understanding of the protocol; counseling the investigator on body scoring, distress, and humane endpoints; and ensuring all mice receive body scoring to avoid distress due to ascites. Any future violations may result in suspension of animal use privileges for this investigator.

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



Camille P. Wicher, Ph.D. Esq., RN, MSN.
Vice President Corporate Ethics
Roswell Park Cancer Institute
Elm & Carlton Sts
Buffalo, New York 14263
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A3143-X

New case
No prelim.

January 3, 2020

Axel Wolff, DVM.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

SENT VIA E-MAIL only

RE: Reports of Non-Compliance
1371M and 928M
OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Dear Dr. Wolff,

Please accept the two attached reports 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. 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 (b) (6)

Thank you in advance for your cooperation in this matter.

Sincerely,

Camille P. Wicher, PhD., Esq., RN, MSN
Vice President
Institute Official
OPRR Assurance #A-314301.
USDA Regis. #21-R-032

OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Please accept the following final reports in accordance with 9 CFR 2.31 (c) (3) and (d) (7) Subchapter A of the Animal Welfare Act:

ISSUE: Non-compliance with directive of veterinary staff. Protocol # 1371M

SUMMARY:

The IACUC was informed by the Attending Veterinarian (see below) that a moribund mouse (protocol 1371M) was reported to (b) (6) at 9:00 the morning of November 21, 2019 and that mouse was found dead by LASR veterinary services that afternoon.

Dr. Sexton sent an e-mail at 4:31 pm on November 21, 2019 regarding the mouse that was found dead:

"Hello:

As the contact person responsible for the mice in IACUC protocol 1371, our staff has been reaching out to you to let you know about animals found in distress due to severely distended abdomens due to ascites.

Today a female in room (b) (4) cage # 2 was reported to you first thing in the morning and you indicated that you would come to take care of it but the animal was found dead in the afternoon. In addition your monitoring card indicated the last time you monitored the animal was 11/18. Since this is an ongoing problem and because it is an animal welfare concern I am including Dr. Moser chair of IACUC as a reported incident..."

(b) (6) responded to Dr. Sexton's e-mail at 4:40 pm November 21, 2019:

"Hello

I have come to take care of the mouse at 9 am, however the hood was taken. I did leave a note on the cage today, signed and dated, that I will come back for him in the afternoon as the only time slot I had was after 4:30 unfortunately. I was preparing to go down now..."

IACUC sent a memo to the PI and (b) (6) on November 25, 2019 expressing IACUC's concern with (b) (6) response that she could not euthanize the mouse because someone else was in the hood. Considering that the mouse was in distress (b) (6) should have asked the person working in the hood if she could use the hood for a short period of time to euthanize the mouse or she should have contacted LASR staff to find another location to euthanize the animal (i.e. necropsy room, another procedure room etc.). Waiting was not the appropriate action since this involved an animal in a moribund condition. Another major concern to the IACUC was (b) (6) pattern of not appropriately monitoring and scoring mice with IP tumors. According to the Body Score Card for IP Tumor on the cage the mouse that died was scored on October 22nd, 25th, 31st, and November 8th an 18th. According to the approved IACUC protocol mice with abdominal tumors are to be monitored daily and scored twice a week. The Body Score Card for the mouse that died indicates that scoring was only performed every 8 to 10 days the last three times it was scored. This is a non-compliance with protocol 1371M. Review of past correspondence between LASR Veterinary Services and (b) (6) regarding mice in

January 03, 2020

the same room (b) (4) with IP tumors indicates a consistent pattern of non-compliance with the approved IP body scoring. On October 16th LASR Veterinary Services had to request that (b) (6) euthanize mice with severe abdominal distension. These mice had not been body scored since October 8th. This was again non-compliance with the protocol which states body scoring is to be done 2 times per week. (b) (6) should be appropriately monitoring the mice for moribund and scientific endpoints and following the body scoring frequency stated in the protocol. LASR Veterinary Services should not have had to notify (b) (6) that animals need to be euthanized

The IACUC requested a corrective and preventative plan of action (CAPA) to prevent recurrence of (b) (6) non-compliance with protocol 1371M. The CAPA was received from the PI on December 16, 2019. The CAPA stated the following:

1. (b) (6) will retake AALAS online training and quizzes.
2. (b) (6) will be supervised by a senior lab member (to be assigned) regarding mice entered into a study by her and in her absence and seek assistance by a co-worker listed on 1371M when she is unable to monitor or score her mice.
3. (b) (6) will be required to re-read IACUC protocols 1371M and 1367M including all amendments and sign an affidavit stating so (done)
4. Body Scoring procedure, importance of Body Scoring and signs of animal distress and humane endpoints will be discussed and reviewed with (b) (6)
5. To assure mice will not suffer undue stress due to abdominal distension, each mouse entered into study by (b) (6) will be assessed as per LASR SOP 12.7 for Body Scoring and as specified in 1371M and by using Body Score Cage Card.
6. Additional animal welfare violations by (b) (6) will justify removal from IACUC protocols.

(b) (6) completed the online AALAS training and quizzes, reviewed the Body Scoring SOP, has reviewed the body scoring procedures and signs of distress and has signed the affidavit affirming these actions signed 12/19/2019.

The IACUC committee feels that the CAPA addresses sufficiently the root causes, the corrective plans needed and the preventative processes to prevent a recurrence of this non-compliance by (b) (6). The IACUC believes that (b) (6) understands the importance of following animal protocols, properly performing body scoring, timely response(s) to a LASR Veterinary Services request(s), and the signs of pain and distress in laboratory mice. The IACUC believes this an animal welfare concern and therefore may be reportable.

As IO I concur with the IACUC's findings and corrective actions.

Respectfully submitted,

(b) (6)

Camille P. Wicher, Ph. D. Esq. RN MSN
Institutional Official
Vice President
Roswell Park Cancer Institute

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 06, 2020 7:38 AM
To: Wicher, Camille; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moser, Michael
Subject: RE: Reports of non-compliance

Thank you for this report Dr. Wicher. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Wicher, Camille [mailto:Camille.Wicher@RoswellPark.org]
Sent: Friday, January 03, 2020 1:44 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Moser, Michael <Michael.Moser@RoswellPark.org>
Subject: Reports of non-compliance

Dr. Wolff, Attached please find two reports. One is for non-compliance (1371M) and the other for use of expired medications (928M). If you have any questions please do not hesitate to contact me. Happy New Year! Camille

Camille P. Wicher, Ph.D., Esq. MSN, RN
Assistant Professor of Oncology
Vice President
Roswell Park
Elm & Carlton Sts.
Buffalo, New York 14263
(b) (6)

