



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
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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

July 19, 2018

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

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 July 16, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Roswell Park Cancer Institute. According to the information provided, OLAW understands that on March 26, 2018 the Attending Veterinarian observed a PI's staff member removing a tumor from a mouse under general anesthesia without using aseptic technique and without providing saline, heat, eye lubricant or analgesia. The animal was euthanized upon instruction from the AV. It was not stated if this activity was PHS funded.

The IACUC revoked the lab member's access to the Laboratory Animal Shared Resource (LASR). Reinstatement of animal research privileges would depend on completion of a corrective plan of actions which included retraining of the lab member with both online and wet lab courses. In addition, the PI agreed that there will be a review of all animal experiments every six months and a review of animal experiments prior to initiation at a lab meeting. There will be a second vial of analgesic as a back-up. The lab member in question will be in charge of monitoring expiration dates of analgesics and all compounds and drugs used in animal work by the lab. This lab member will also report quarterly at lab meetings regarding such inventory as well as status of other corrective measures and on the reduction or elimination of any animal related issue. The IACUC also requested that all IACUC protocols be reviewed with all new laboratory personnel and the review be documented.

OLAW appreciates the prompt consideration of this matter by the Roswell Park Cancer Institute, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. In future reports, please include whether or not the activity was PHS funded. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



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-Q

July 16, 2018

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

RE: Report of Non-Compliance
Conduct of animal related activities
without IACUC approval

Dear Dr. Wolff,

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. 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 report in accordance with 9 CFR 2.31 (c) (3) and (d) (7) Subchapter A of the Animal Welfare Act:

ISSUE: failure to use analgesic/aseptic technique

SUMMARY:

The IACUC was informed by Dr. Sandra Sexton, the Attending Veterinarian (see below e-mail from Dr. Sexton 03/26/2018) that a member of a PI's laboratory had not used aseptic technique or analgesia on a mouse that was undergoing surgery to resect a tumor. Dr. Sexton observed a mouse that had resected a tumor that was still under general anesthesia. The incision site was closed with surgical clips. Dr. Sexton's e-mail stated:

"I want to report an animal welfare incident today with one of PI's staff. He was doing surgery in CCC Bio Bubble B and he was not using aseptic technique or analgesia. He was removing tumors and the animals did not receive saline or heat or analgesia. The animal he was working on had already been closed with surgical clips and there was blood on the skin. When asked he then said that the analgesia was being used by another person in his lab. I asked him to please stop doing any other animals until he was prepared and then I proceeded to call the PI. The PI said he would talk to him. After I spoke to the PI, the lab member said that he was going to remove the tumors and euthanize the animals, so I questioned why was the incision closed if it was a terminal and he did not know what to respond. I instructed to euthanize that animal and he did. He returned the other animals to the cage. There was no evidence of eye lubrication, heat or hydration either..."

Upon receiving the e-mail IACUC notified the PI that it was revoking the lab member's access to the Roswell Park Laboratory Animal Shared Resource (LASR) until the IACUC could investigate and determine the appropriate actions needed to prevent a reoccurrence of such an event. In addition, IACUC notified the PI that in order to regain privileges to perform animal research and have access to the Laboratory Animal Shared Resource (LASR) the lab member will have to retake both the online IACUC Training and IACUC surgical wet lab course. This retraining could begin immediately but the lab member would not have access to LASR or be permitted to perform any animal research until after review of the incident by the IACUC. As part of any animal welfare issue the IACUC requests that the PI perform a root cause analysis to determine why this issue occurred and provide a plan of action in response to this issue and a plan of correction to prevent a recurrence (CAPA) of this type of event.

Plan of Correction:

The PI acknowledged that he also took this issue very serious as well. The approved CAPA was as follows:

1. retake the online IACUC Training and IACUC wet lab training.
2. retake the LASR surgical wet lab course.

3. Education and review of all animal experiments and procedures will be discussed every 6 months at lab meetings in order to keep everyone apprised of approved procedures.
4. review the animal experiment prior to the initiation of that animal experiment among all personnel on the approved protocol at lab meeting.
5. There will be an alternate source for analgesics (which are provided by LASR) when one of the vials is in use by another investigator in the lab. (i.e. a second vial as a backup).
6. This lab member will be in charge for review and monitor for expiration of analgesics as well as all compounds and drugs used in animal work by the lab.
7. this lab member will report quarterly at lab meetings the success of the CAPA and the metrics are being monitored to determine the success including, documentation of receipt of analgesics and return of expired analgesics, the elimination of any recurrence of the event as well as reduction or elimination of any animal related issue.

This CAPA was presented to the IACUC committee at the April monthly meeting (04/10/2018). In addition to the CAPA presented to the committee the committee requested that all IACUC protocols be reviewed with all new laboratory personnel. So # 8 was added to the above: All animal protocols will be reviewed with all new personnel and the review of the protocols with the new personnel will be documented.

The IACUC believed this was an animal welfare concern and therefore may be reportable. It should be noted that the animal did not recover from the surgery and therefore the surgery became a terminal surgical procedure. The other animals in the cage did not undergo any surgical procedures.

If you have any additional questions, require clarification or further action at this time please feel free to contact me.

Respectfully submitted,

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: Tuesday, July 17, 2018 9:09 AM
To: Wicher, Camille; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: report 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: Monday, July 16, 2018 5:03 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: report of non-compliance

Dr. Wolff, please accept this report of non-compliance regarding a failure to follow IACUC protocol issue. thank you in advance. 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)

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