



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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6700B Rockledge Drive  
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Bethesda, Maryland 20817  
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April 14, 2020

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

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 a February 5, 2020 letter, received in our office on April 3, 2020, 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 January 3, 2020 a veterinarian observed a cage of four mice that had undergone bilateral tumor resection and improper placement of wound clips resulting in the mice not being able to move the rear limbs normally. Although Marcain had been administered per the cage card, buprenorphine had not. In addition, the surgeon was not identified on the cage card. The veterinarian administered buprenorphine. When contacted, the PI stated that the surgeon would not perform further surgeries without training and that the PI would request that the animals be euthanized that day. Additional information regarding the incident was requested by the IACUC. It was stated that this activity was not PHS funded.

Corrective and preventive measures included a training plan for the surgeon responsible for the incident. The surgeon left Roswell Park before the plan was initiated. Other measures taken by the PI were:

- Semi-annual review at laboratory meetings of IACUC protocols and training including the post-surgical care and adherence to IACUC protocols.
- Review at a laboratory meeting of an animal experiment prior to initiation of that animal experiment among all laboratory personnel on the approved protocol.
- Review and monitoring of expiration of analgesics as well as all compounds and drugs used in animal work by the lab.
- All animal protocols will be reviewed with all new personnel and the review of the protocols with the new personnel will be documented.

Page 2 – Dr. Wicher  
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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. 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: 2020.04.14 15:09:39 -04'00'

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

cc: IACUC Contact



A3143-1B

**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  
Mike.Moser@roswellpark.org

(b) (6)

**To: Camille Wicher, Ph.D., RPCI Institute Official**  
**From: Michael T. Moser, Ph.D., Chair RPCI IACUC**  
**DATE: February 5, 2020**  
**Re: Non-Compliance with IACUC protocol 1203M: Bilateral Tumor Resection**

This memo is to report a non-compliance animal welfare incident that occurred on January 3, 2020. A LASR Clinical Veterinarian notified IACUC at their monthly January meeting (01/07/2020) of an animal welfare concern involving protocol 1203M involving four mice in a cage in CCC (b) (4) that had surgical procedures performed that morning. The mice were observed by the veterinarian to have bilateral tumor resection. Three of the four mice in the cage were covered in blood and the placement of wound clips made it difficult for the mice to move their hind legs. She reported that the surgical incision was too large and the number of wound clips was excessive. The bilateral tumor resection from the underside of the mice was not compliant with protocol 1203M which only permitted a single SQ implantation of tumor cells and resection of the SQ tumor. The name of the person that had performed the procedure was unknown since the information regarding the surgeon on the surgical card was blank. The mice had been given Marcain, however buprenorphine was not administered as required in the protocol (a second non-compliance issue.). At 3:00 pm on the date of surgery (the 01/03/2020) the veterinarian administered buprenorphine to all four of the mice. (b) (6) then contacted the PI about the mice via e-mail at 3:11 p.m. and he promptly replied in an e-mail at 3:55 p.m. The PI replied in the e-mailed that another doctor was the researcher that had performed the surgery and that he would request that the mice be euthanized that day. The PI also assured the veterinarian that the doctor involved would not perform any surgical procedures before receiving retraining. The mice were euthanized that day. The IACUC appreciated the PI's timely response and immediate plan of correction of euthanizing the mice and not permitting the doctor involved to perform any surgical procedure until he receives retraining.

The IACUC after discussion of this incident at the January meeting requested additional information and clarification regarding this incident (memo 01/15/2020):

- The description of the surgical procedure and the approximate time that the procedures were performed January 3, 2020.
- Any additional individuals (if any) that were involved in those surgical procedures
- Confirm if this is a PHS funded experiment.
- Any additional information you deem relevant to the investigation.

Additionally, the IACUC requested that the PI provide a corrective and preventative plan of action to prevent a recurrence of this type of incident that included:

- retraining (i.e. retaking the AALAS online training and quizzes including the surgical module).
- The doctor involved, after completion of the online training, is required to be retrained by LASR Veterinary Staff in surgical procedures and pre and post-operative care.
- After approval to perform surgical procedures by the LASR Veterinary Services, must be supervised by a senior laboratory member at least the first 5 times (procedure days) he performs surgical procedures and documentation of the supervision be provided to the IACUC. In addition, the IACUC recommends increased supervision by senior laboratory staff for all animal associated duties until (b) (6) clearly demonstrates the ability to comply with IACUC protocols.

The PI replied promptly (01/26/2020) to IACUC's request for additional information and CAPA.

- The surgical procedure performed was resection of mammary gland tumors from 2 mammary gland sites (bilateral mammary tumors).
- The time the surgeries had been performed was approximately 11 am – 12 pm on January 3, 2020.
- The doctor in questions was the only person involved with the surgeries.
- PHS funding was not the source for the funding for this preliminary study.

The PI's corrective plan of action included the 3 requests by the IACUC regarding retraining and oversight (see above). In addition to his initial corrective plan that the mice be euthanized that day (01/03/2020) and that no surgical procedures would be performed before receiving retraining. The PI's preventative plan of actions included:

- Semi-annual review at laboratory meetings of IACUC protocols and training including the post-surgical care and adherence to IACUC protocols.
- Review at a laboratory meeting of an animal experiment prior to initiation of that animal experiment among all laboratory personnel on the approved protocol.
- Review and monitoring of expiration of analgesics as well as all compounds and drugs used in animal work by the lab.
- The doctor in questions will report quarterly at laboratory meetings the success of the CAPA and the metrics 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.
- All animal protocols will be reviewed with all new personnel and the review of the protocols with the new personnel will be documented.

On January 28, 2020 the IACUC received an e-mail from the PI reporting that the doctor in question had decided to take another position and was leaving Roswell Park (01/31/2020). The IACUC committee feels that the PI's CAPA addresses sufficiently the root causes, the corrective plans needed and the preventative processes to prevent a recurrence of this non-compliance. Although the doctor in question never completed retraining or the other outlined requirements the IACUC feels that had he not left Roswell Park the CAPA was appropriate to prevent a recurrence of the non-compliance. The IACUC believes this was an animal welfare concern and therefore may be reportable. If you have any additional questions, require clarification or further action by the IACUC please feel free to contact me.

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, April 6, 2020 7:44 AM  
**To:** Wicher, Camille  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reports of non-compliance 1203M

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

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

**From:** Wicher, Camille <Camille.Wicher@RoswellPark.org>  
**Sent:** Friday, April 3, 2020 12:37 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Moser, Michael <Michael.Moser@RoswellPark.org>  
**Subject:** RE: Reports of non-compliance 1203M

Dr. Wolff, Please find attached a report of non-compliance from Roswell Park Cancer Institute.  
OPRR #A-314301  
USDA #21-R-032

Thank you.

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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