



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

March 27, 2019

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

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 March 21, 2019 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, OLAW understands that mice were not given post-operative analgesia as stated in the approved protocol.

The corrective actions consisted of retraining the Principal Investigator and laboratory staff, having the staff certify understanding of the content of the protocol, and having the PI monitor provision of drugs.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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

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

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

ISSUE: failure to comply with protocol.

SUMMARY: During the IACUC semi-annual inspection it was observed that 3 surgical cage cards for PI's protocol UB1301M indicated a surgery but no analgesia was noted on the cards. Protocol UB1301M (section 8E) states "carprofen will be administered once every 24h post-surgery for 48 hours (and more if needed). The IACUC sent a memo to the Dr. B requesting additional information regarding surgical procedures performed and what analgesic was used on these mice.

The PI responded: a member of my group has performed unilateral sciatic nerve transection on the mice in question (GLUT1 (flox/flox) and GLUT1 (flox/flox) x P0-Cre) using deep isoflurane anesthesia. Following the surgery, the animals were transferred from the Biobubble to (b) (6) and surgical cage cards (violet cards) were used to mark the cages with these mice recovering from the intervention. Because my student intended to collect nerve tissue 24 hours following surgery at the experimental endpoint, and no postoperative signs of discomfort were noticed, the analgesia was overlooked and no carprofen was administered. However, we all fully recognize that carprofen should have been administered before the recovery (directly after the surgery) as outlined in Section 8-E of our protocol.

INVESTIGATION:

The event and all the pertinent information including the CAPA was presented to the full IACUC committee. The IACUC accepted the CAPA but requested that the all personnel including the PI that perform surgical procedures (unilateral sciatic or femoral nerve transection and crush injury procedures) retake the online AALAS surgical training module and take the LASR surgical wet lab. The committee considers this both a welfare concern as well as a non-compliance with the approved protocol UB1301M.

The PI provided the following CAPA: (I)have implemented a preventative plan of action, which includes:

- 1) While the IACUC protocol UB1301M is always available to all members, everyone in the lab will carefully re-read it biannually, and sign a document stating that its content is fully understood.
- 2) I will personally keep a copy of every request of substances from the DLAR vet techs, and check on the use of these substances (volumes).

Full IACUC committee decision:

March 21, 2019

The incident and CAPA was reviewed by the full IACUC committee.

- The incident was determined to be consistent with serious non – compliance with PHS policy.
- The IACUC approved the PI's submitted plan of correction.
- The NYS Inspector approved the plan of correction.



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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e-mail: camille.wicher@roswellpark.org

March 21, 2019

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: Reports of Non-Compliance
OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Dear Dr. Wolff,

Please accept the enclosed 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, Ph.D., Esq., RN, MSN
Vice President
Institute Official
OPRR Assurance #A-314301.
USDA Regis. #21-R-032

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 22, 2019 8:11 AM
To: Wicher, Camille
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: non compliance reports

Sensitivity: Confidential

Thank you for these reports, Dr. Wicher. In future please send noncompliance reports promptly after the matter has occurred rather than combined later in a group. Also make sure that you have signed them.
Axel Wolff

From: Wicher, Camille <Camille.Wicher@RoswellPark.org>
Sent: Thursday, March 21, 2019 11:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: non compliance reports
Sensitivity: Confidential

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Dr. Wolff, please accept these reports of non-compliance.

Please advise if there is anything else that needs to be done. These occurred over the last several months 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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