



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

November 6, 2019

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

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 October 31, 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 being euthanized by an individual not listed on the protocol. The veterinarian had directed a laboratory staffer to euthanize some ill mice but this was not immediately done and the animals' health declined. The veterinarian again directed the staff to immediately euthanize the mice and this is when an unauthorized individual performed the procedure, which was done correctly.

The corrective actions consisted of amending the protocol to include all personnel, counseling the investigators on having only staff listed on the protocol perform animal activities, and having the laboratory staffer undertake retraining to reinforce the requirement to follow veterinary orders.

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

A3143-W



Camille P. Wicher, Ph.D. Esq., RN, MSN.
Vice President Corporate Ethics
Roswell Park Cancer Institute
Elm & Carlton Sts
Buffalo, New York 14263
Phone: 716-845-7647
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e-mail: camille.wicher@roswellpark.org

October 31, 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,

(b) (6)

Camille P. Wicher, PhD., Esq., RN, MSN
Vice President
Institute Official
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 1: Unlisted personnel performed protocol procedure

SUMMARY:

The IACUC was informed by the Attending Veterinarian (see attached e-mail 09/03/2019) that mice were being euthanized by someone not listed as personnel on protocol 1282M.

Dr. O was the PI on protocol 1282M. Dr. T is the co-I of the protocol. (b) (6) the listed contact for 1282M, was instructed to euthanize the mice enrolled in Dr. O's protocol 1282M. The Veterinarian made this request to (b) (6) and Drs. O and T. On August 29th, (b) (6) responded to the veterinarian's request to euthanize some animals with ulcerations and to monitor some others, stating (b) (6) we will definitely monitor them closely and euthanize". (b) (6) sent another e-mail on September 3rd stating the mice that she had requested to be euthanized were still in the room and looked worse and needed to be euthanized that day (September 3, 2019). The e-mail from (b) (6) also requested to know who the PI for the project was since Dr. O was no longer at Roswell (last day August 12, 2019). (b) (6) did not respond to the e-mail from (b) (6). However, Dr. T did send (b) (6) to LASR to euthanize those mice.

When (b) (6) entered the procedure room, (b) (6) found (b) (6) from Dr. T's lab euthanizing the mice. (b) (6) had appropriately euthanized the mice, however (b) (6) was not listed as personnel on 1282M. (b) (6) is listed as personnel on all protocols which Dr. T is a PI and is approved to euthanize mice.

Dr. T did not request to become the PI of protocol 1282M and add (b) (6) as personnel on the protocol until after the euthanization of the mice (09/06/2019). This incident was reported to the IACUC Committee at the September monthly meeting (09/10/2019) and the committee approved Dr. T as the PI of 1282M and discussed the event. The committee agreed that (b) (6) had done the appropriate action by euthanizing the mice however it is still a reportable event since (b) (6) was not listed as personnel on the protocol at the time.

Plan of Correction:

The IACUC requested that (b) (6) the listed contact for the mice on protocol 1282M, retake the AALAS training (Working with the Laboratory Mouse and Working with the Roswell IACUC) since she had not responded in a timely manner to LASR Veterinary Services requests regarding the health status of the mice on protocol 1282M and the request to euthanize them. The IACUC feels that retraining of (b) (6) will refresh and

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reinforce the importance and need for a timely response to veterinary services inquiries and concerns for the welfare of their research animals.

(b) (6) completed her retraining on October 2nd. Dr. T and (b) (6) were re-educated as to the fact that only listed personnel can perform procedures on a protocol. The IACUC requires no further action from Dr. T or personnel on 1282M.

Respectfully submitted,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 1, 2019 7:10 AM
To: Wicher, Camille
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of non-compliance

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: Thursday, October 31, 2019 2:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Moser,
Michael <Michael.Moser@RoswellPark.org>
Subject: Report of non-compliance

Dr. Wolff, attached please find a report of non-compliance. If you have any questions, please do not hesitate to contact me. 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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