



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

June 11, 2019

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

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 letter dated May 31, 2019 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the Roswell Park Cancer Institute. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that a principal investigator failed to provide water to two cages of mice held overnight in an incubation chamber. The lack of water may have contributed to the death of one mouse, though because the mouse had other clinical issues, this could not be definitively determined. The principal investigator acknowledged the error and proposed corrective action consisting of reminder signage on the incubation chamber. The Institutional Animal Care and Use Committee (IACUC) evaluated and accepted the corrective measure, and in addition required a log documenting transfer of animals to the incubator that includes initials, dates and confirmation that water is provided.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
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
Phone: (b) (6)
Fax: (b) (6)
e-mail: camille.wicher@roswellpark.org

A3143-U

May 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: Report of Non-Compliance
Incubator Incident

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 as per the attached document. 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: Incubation chamber Protocol #M480

SUMMARY:

The IACUC was informed by LASR attending veterinarian of an adverse event that occurred involving the death of mouse in an incubation chamber (protocol M480) A mouse was found dead in a cage five of mice that had been transferred by the researcher to an incubator chamber the previous afternoon (~5:00 pm) by LASR staff during the morning health check.

The cage did not have a water bottle and there was no other source of water available in the incubation chamber. It could not be confirmed if the animal died due to lack of water since the other mice in the cage appeared healthy but lack of access to water may have been a contributing cause. A second cage had also been transferred without a water bottle, but all those mice appeared healthy. The PI stated in her e-mail that she had transferred the two cages of mice into the incubation chamber and she was responsible for not putting water bottles in the cages.

The PI took full responsibility for the incident. The PI acknowledged that she knew mice not housed on standard ventilator racks need water bottles provided but she just forgot to add water bottles. To prevent a recurrence of this unfortunate event her laboratory will place a notice on the front of the incubator stating that all cages housed in this incubator chamber require water bottles.

Additional investigation into the event identified other factors that may have contributed to the death of the mouse. Age of the mouse could have been a contributing factor since the mouse was over two years old. The health status of the mouse since the mouse had a spontaneous tumor and was likely already stressed. Therefore, although lack of access to water as the cause of death could not be confirmed it was likely a contributing stress factor.

This adverse event was reported to the IACUC and discussed. The IACUC accepted the corrective plan of action. In addition the IACUC determined that a log should be placed on all the incubator chambers in LASR that document when animals are transferred into the incubator chamber for the initiation of an experiment and that the date and initials of the person transferring the cage(s) confirm (by a check box) that the cage(s) has a water bottle.

CORRECTIVE ACTION:

The IACUC approved the CAPA and required no further actions. This was an unfortunate event caused by human error. The signage that water bottles need be placed in cages should be sufficient to eliminate a recurrence this event. In addition the

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Roswell Park Cancer Institute
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documentation of cage transfer and confirmation of water bottles in cages by the new LASR log sheet should prevent any such events by all users of the incubation chambers.

The IACUC determined this event was an animal welfare concern because the animals were deprived of water and ultimately one of the mice in the incubation chamber died.

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: Monday, June 03, 2019 12:12 PM
To: Wicher, Camille; 'olawdco@mail.nih.gov'
Cc: (b) (6)
Subject: RE: report of non-compliance

Thank you for sending 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Wicher, Camille [mailto:Camille.Wicher@RoswellPark.org]
Sent: Friday, May 31, 2019 3:54 PM
To: 'olawdco@mail.nih.gov'
Cc: (b) (6)
Subject: report of non-compliance

Dr. Wolff, attached please find a report of non-compliance. 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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