



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

July 19, 2018

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

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 and your institution's own internal policies at the Roswell Park Cancer Institute. According to the information provided, OLAW understands that in January 2018 an Everon Biosciences employee was observed carrying three mice cages wrapped in cloth between buildings. The cages contained a total of eight mice. This action was in violation of your institution's SOP regarding the transport of animals. The PI and co-I for the associated project were notified and transport of mice was suspended pending resolution of the issue. It was not stated if this activity was PHS funded.

A corrective plan of actions included counseling and retraining of Everon employees regarding this issue. They were instructed to minimize transport of animals from the animal facility whenever possible. It is understood that Everon has made other arrangements rather than transport the mice, which the IACUC has reviewed and approved. It is further understood that the animal transport SOP is under review for improvement including the possible use of transport cages instead of transporting animals in their home cages.

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. We also acknowledge the effort taken to investigate the conditions under which the animals were transported in January 2018. We find no reason to believe that those animals experienced elevated pain or distress or other animal welfare issues from that brief exposure. 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

Obtained by Rise for Animals. Uploaded 07/09/2020



Camille P. Wicher, Ph.D. Esq., RN, MSN.
Vice President Corporate Ethics
Roswell Park Cancer Institute
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Buffalo, New York 14263
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A3143-P

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

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: Inappropriate transport of animals.

SUMMARY:

The IACUC was informed that on a Tuesday morning in January of 2018, a Roswell Park employee observed a gentleman leaving one of our buildings through the west entrance and was heading to another building carrying what looked like mouse cages wrapped in yellow cloth. Upon investigation by Dr. Sexton, the Attending Veterinarian, the gentleman was identified as an employee of Everon Biosciences, a RPCI subsidiary governed by our IACUC.

Dr. Sexton contacted the employee and requested that he meet with her to discuss the issue. Dr. Sexton relayed the following regarding the conversation:

"I asked him if he had taken mice out of the building and he said yes that he needed to collect tissues that day and had a very busy day ahead of him so he decided to take them to their lab. He said others in his lab have done this before and that he didn't think it was too cold. He took 3 cages with 5 mice in one 2 in the other and 1 in the last one. I asked if he could have collected the tissues in LASR and then take them to Everon for processing and he said yes that they had done that before too."

The employee was informed that the transport of the mice in this manner is a violation of SOP 5.3 regarding proper transport of laboratory mice wherein it is specified how to transport animals during cold weather to prevent harm to the mice.

The transport of mice is approved in protocol 1230M. When the outside temperature is below 64°F transport of mice not using the LASR van is in violation of the SOP 5.3: Transport of animals. The IACUC sent a memo to the PI's regarding the event. The IACUC requested that the PI and Col provide a corrective plan of action and a plan to prevent a recurrence of this type of incident (CAPA) so that it could be reviewed at the February IACUC meeting. Transport of mice was suspended pending resolution of the issue.

Plan of Correction: The IACUC received the corrective plan of action and a plan to prevent recurrence of the incident. The response included the following:

" To prevent this situation from happening in the future, Everon employees working in the animal facility have been informed of this incident during a special meeting on January 17th, and have also received a copy of the transport SOP... In addition, Everon employees were instructed to minimize transportation of animals from the animal facility whenever possible. To do so, several options were discussed including the use of a collaborator's space and a LASR site. Dr. Sexton also mentioned that special equipment needed for Everon's research could be made available in the animal facility. "

Notification of the incident and the CAPA was presented to the IACUC at the February meeting of the full committee (02/06/2018). During the deliberations it was discussed that the LASR SOP 5.3 be updated to reflect the use of shipping containers for transport of mice outside Roswell Park buildings instead of regular cages to reduce the risk of cages opening and mice escaping. When the incident was discussed at the March 6th meeting the IACUC decided to request justification from Everon Biosciences for transport of mice to their Ellicott Street Laboratory. During the IACUC's discussion of the incident there was concern if there were any animal welfare issues caused by the transport of the mice on January 9th 2018. Since the IACUC and LASR did not become aware of the event until January 11th and therefore the IACUC cannot determine if any animal welfare issues arose because of transport.

After review of the available literature on transport of mice and temperature the only information IACUC could find was from Marquette University's IACUC "special precautions or postponements are required when temperatures are below 45° F or above 85° F. At these temperatures, the welfare of the animals is jeopardized." and from University of Illinois "Temperature extremes must be avoided. Special precautions must be taken to protect animals from heat or cold stress when climatic temperatures are inappropriate for the species (e.g., below 45 F or about 85 F)." Review of Buffalo's weather history reports that the temperature on the morning of January 9th was 29 °F. These mice were in their plastic cages and covered with a yellow cloth. The distance according to Google Maps from 645 Virginia St (CGP building entrance) to 640 Ellicott St (The Innovation Center entrance) is 0.2 miles and the walk takes 3-4 minutes. Considering the animals were covered and the only opening was on the top of the cages. We do not know if the temperature would have changed significantly during transport. Additional information found regarding temperature and mice came from a 2006 ILAR whitepaper: Shipping Rodents and Rabbits ([nas-sites.org/ilar.../files/.../WHITE-REDACTED-RODENT-TRANSPORTATION.pdf](https://www.nationalacademies.org/ilar/files/.../WHITE-REDACTED-RODENT-TRANSPORTATION.pdf)) which has a graph that shows thermoregulatory effector responses that indicates that an ambient temperature of -1.6° C (29°F) is in the range of normothermia.

We do not know whether the mice transported on January 9th were adversely affected and if this event caused any animal welfare issues. None were reported during follow up. IACUC believes that the temperature guidelines listed for rodent transport are for longer exposure times than the elapsed time that occurred on January 9th (3-4 minutes) and are for longer distance truck and airline transport conditions for commercial couriers and transport between institutions and within larger institutions with a greater footprint than Roswell Park.

The IACUC committee believes that the CAPA addresses sufficiently the root causes, the corrective plans needed and the preventative processes to prevent a recurrence of this non-compliance with the LARS Transport SOP 5.3. The IACUC has not closed this issue as it is awaiting a response from the PI to a memo requesting justification for the need to transport mice to their Ellicott Laboratory Facility. If the IACUC determines that Everon Biosciences can transport mice to their Ellicott Street Laboratory the IACUC will then send a revised LASR SOP 5.3 for transport that will address any specifics required for outside transport of mice by Everon Biosciences.

Follow up: Everon has made other arrangements rather than transport the mice, which the IACUC has reviewed and approved.

Page 3 of 3
Roswell Park Cancer Institute
July 10, 2017

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 9:10 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 4:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: report of non-compliance

Dr. Wolff, please accept this report of non-compliance regarding a transport issue. Although we do not know if there was any actual harm to the animals, the potential was there and thus I am reporting it. 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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