



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
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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 R]

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 two instances 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 the following about the incidents and the corresponding corrective actions:

- 1) Rodent surgery was not being conducted aseptically.

Corrective action: The technician responsible was instructed to stop performing additional surgeries. The technician was unable to demonstrate proficiency and will no longer be allowed to perform mouse surgeries. All laboratory staff was retrained and the laboratory was placed under enhanced post-approval monitoring.

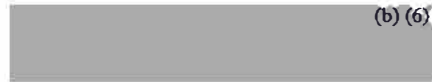
- 2) Expired high fat and control diets were fed to mice.

Corrective action: The laboratory staff was counseled on feeding in-date feed only, feed will be subdivided into smaller amounts and placed in labeled bags in the freezer or refrigerator, and feed usage will be monitored by laboratory and animal care staff. Due to a shortage of the diet, the Institutional Animal Care and Use Committee (IACUC) allowed feeding of the expired chow until new stock is obtained. Because the food had been frozen, it is believed that it was still viable. The Principal Investigator will destroy the old diet once the new one arrives and inform the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. While OLAW generally agrees with the actions taken by the IACUC to comply with the PHS Policy, we caution that the feeding of expired food, just as with using expired drugs, has the potential to impact animal welfare and to negatively impact the study. Performance standards can be used whereby the diet is nutrient tested and could be fed if found to be acceptable. Rigor and reproducibility of the study could be affected in not adhering to the protocol by using expired substances. Thank you for informing OLAW about this matter.

Page 2 – Dr. Wicher
March 27, 2019
OLAW Case A3143-R

Sincerely,

 (b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

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: NYS Inspection revealed two deficiencies. 1.) failure to use aseptic technique; 2.) use of expired diet.

SUMMARY: The committee agreed unanimously that it was seriously non-compliant with the regulations and the activity was suspended until there was compliance with applicable regulations.

INVESTIGATION:

1. During a NYS inspection a clinical research technician was found to be using improper aseptic technique during a rodent survival surgery.

- The attending veterinarian, principle investigator (PI) and IACUC were notified.
- Immediate steps were taken to remove this technician's ability to perform surgery on the animals until rehabilitative action could be taken.
- The PI was cooperative and put in a corrective action plan (CAPA)

Full IACUC committee decision:

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.

Subsequent to the full investigation, the committee imposed the following actions:

- The technician will no longer be able to perform surgeries as she did not demonstrate on retraining the surgical skills required for rodent survival surgery.
- All lab personnel approved to perform mouse surgery will undergo a refresher course in principles of rodent surgery both AALAS and wet lab. PI's animal research would be subject to unannounced IACUC inspection during the next twelve (12) months.
- The IACUC approved the PI's submitted plan of correction.
- NYS Inspector approved the plan of correction.

2. Use of expired diet

- During the NYS inspection it was determined that an expired high fat mouse diet and control diet was being fed to mice.

- The attending veterinarian, principle investigator (PI) and IACUC were notified.
- The PI was cooperative and put in a corrective action plan (CAPA) which included:
 - a. Inform lab personnel of the inspection violation noted.
 - b. Reinforce with lab personnel the necessity of discarding expired mouse chow and feeding mice with unexpired mouse chow only.
 - c. Orders of irradiated high fat and control chow in 12.5 kg boxes will be subdivided into 1 kg sterile bags to be stored in LASR freezers or refrigerators as per manufacturer's storage recommendations. Bags will be labeled with PI name, protocol number, name of diet, and expiration date.
 - d. Chow usage will be monitored both by lab personnel and LASR caretakers."

Full IACUC committee decision:

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.
- Due to ordering and shipment of the special diets, the PI did not have the ability to obtain the custom diet in a timely manner. At a specially convened meeting the IACUC granted the PI:
 - permission to continue to feed the expired diets to the mice already enrolled in the experiment until the shipments of new lots of the diets are received. Although feeding expired food is a violation, the IACUC, after deliberation, determined that it was better to continue feeding the expired diet than it was to remove the animals from the experiment or to change to a different formulation of the diet and potentially jeopardize the experiment. The stocks of the diets were kept frozen prior to use which most likely delayed the breakdown of nutrients associated with storage (expiration date equal to 6 months from the date of manufacture when stored in a cool, dry area). There is no way to confirm the integrity of the diets without sending them out for nutrient testing. The IACUC believed although nutrient testing of the diets is plausible it was not a realistic solution. The IACUC determined since the diets expired in June of 2018 and have been and are currently being fed with no apparent detrimental effects (i.e. no effects on weight gain) continuing to feed the expired lots of the diets until the new lots of diets are received (already ordered) should not have an adverse effect on the welfare of the mice.
- The IACUC requested that as soon as PI receives the new shipment of the diets that old lots of diets be destroyed immediately and feeding the new lots of the diets be initiated. Additionally the IACUC requested notification when the new lots of the diets are received and feeding of the new lots of diet initiated and after discarding the expired lots of diets.
- The IACUC approved the PI's submitted plan of correction.
- The NYS Inspector approved the plan of correction.

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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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, PhD., Esq., RN, MSN
Vice President
Institute Official
OPRR Assurance #A-314301.
USDA Regis. #21-R-032