



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 T]

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 laboratory member deviated from an Institutional Animal Care and Use Committee (IACUC) approved protocol. The laboratory member performed bone marrow transplants from an unspecified number of donor mice into two recipient mice on study. This procedure was not in the IACUC approved protocol.

Corrective measures included submission of an amendment to the protocol, which was approved by the IACUC. Additional measures included improved oversight by the principal investigator, development of a table to track protocols, and training for all new lab members going forward. The IACUC found the corrective measures proposed by the principal investigator to be appropriate, and no further actions were required by the Committee.

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. For future reports, please remember to include dates of occurrence when describing an incident and if possible, please include the exact number of animals affected, including donor animals involved in transplantation procedures. In addition, if this activity was PHS funded, please ensure that no charges are made to the PHS grant for any unauthorized animal activities.

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)
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e-mail: camille.wicher@roswellpark.org

A3143-T

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
Non- IACUC approved procedure

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, Ph.D., 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: Non-IACUC approved Procedure Protocol # 1264

SUMMARY:

The IACUC was informed that a non-approved procedure was performed under IACUC protocol 1264M. The IACUC was informed that during a congruency review of the annual progress report for PI's grant with the approved IACUC protocol 1264M, a procedure reported in the progress report was not included in the approved protocol. The reviewer, the Executive Director of the Office of Research Subject Protection sent an e-mail to PI inquiring about the incongruence between the 2 documents.

"...The report describes transplanting wild type bone marrow in Ssrp1, CreER mice during treatment with tamoxifen. I don't see bone marrow transplantation in 1264M. Please clarify..."

PI responded in a subsequent e-mail that same day:

"...after investigation between me and my former PhD student, now postdoc, we found that this amendment was never submitted..."

Subsequently, an amendment was received in the IACUC Office requesting to add hematopoietic cells isolated from the femur and tibia of the wildtype mice into the tail vein of the experimental mice (bone marrow transfer). All other procedures were already in the approved protocol.

The IACUC sent an e-mail to PI regarding the performance of the bone marrow transplant procedure on mice enrolled on protocol 1264M and that the procedure was not in the approved protocol. PI was asked to provide the number of animals that had received the bone marrow transplant and included a request for an outline of all the procedures that were performed on the mice including the bone marrow transplant (i.e. radiation, drugs, etc.) as well as the experience with bone marrow transplants, training etc. of the person that performed the procedure. A corrective and preventative plan of action (CAPA) was also requested. PI informed that IACUC considered this a reportable event since it involved a procedure that was not in the approved protocol and that the incident including discovery, the submitted amendment, CAPA, and any other facts pertinent to the deliberations of the committee would be presented to the full IACUC committee at the next IACUC monthly meeting.

PI promptly responded to the IACUC via e-mail. Bone marrow transplants had been performed on two mice. None of those mice received radiation treatment only pretreatment with tamoxifen prior to bone marrow transplant to knock out SSRP1 expression in the mice (an approved procedure). The laboratory member that performed the procedure was post-doc who had been trained to perform bone marrow transplant by another laboratory.

A CAPA was received that addressed this procedural oversight.

1. "We discussed these issues in the lab and ran investigation to find the reasons of this incident. We understand that they are not excusable, but there was really no intention to do any of this. I was very busy with grant submission during the last several months and did not oversee very carefully some administrative steps. For example, when my student got excited data and suggested to run experiment to test new hypothesis, I did not remind her that before doing even small pilot experiment she needs to submit an amendment.

2. To avoid this in the future we will do the following:

- We will organize a table for each IACUC protocol in which we will have listed approved experiments and add any new amended experiment. We will have these tables on the lab server and each lab member will be familiar with its location. I will review this table regularly.

- For any new experiment we will make sure that we either have approval from IACUC or we will need to file amendment. I will personally check the status of each experiment and amendment.

- Each new lab member will be trained in how to work with animal protocols and the necessity of having approval for each deviation from the approved protocol will be discussed.

I would like to underline that I am completely responsible for these mistakes and I will do as much as possible to avoid this in the future.

The event and all the pertinent information including the CAPA along with the amendment was presented to the full IACUC committee. The committee decided since the bone marrow transplant involved only an IV injection of cells that this event did not adversely affect the welfare of the animal but that it was reportable since the procedure was not in the approved protocol. The IACUC Committee voted to approve the amendment to 1264M submitted by PI that adds bone marrow transplant to the experimental protocol.

The IACUC committee believes that PI's CAPA addresses sufficiently the root causes, the corrective plans needed and the preventative processes to prevent a recurrence of this non-compliance. The IACUC decided this is a reportable event since the procedure was not included in the protocol 1264M at the time of the incident. The IO concurred.

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 12:14 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 4:06 PM
To: 'olawdco@mail.nih.gov'
Cc: (b) (6)
Subject: report of non-compliance

Dr. Wolff 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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