



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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) 480-3387

March 4, 2020

Re: Animal Welfare Assurance
#A3283-01 (OLAW Case 2R)

Dr. Milan Mrksich
Interim Vice President for Research
Northwestern University
Office for Research
750 N. Shore Drive- Rubloff Bldg. 7th Floor
Chicago, IL 60611

Dear Dr. Mrksich,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 28, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Northwestern University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to provide animals the full regimen of analgesics after a major survival surgery as described in the approved protocol. The final report states that 39 mice underwent intracranial surgical procedures between November 1, 2019 and November 23, 2019. During the IACUC Office staff satellite visit on December 20, 2019 it was found that the post-operative care was not documented as required on the cage side rodent medical record. Investigative results revealed that the animals only received Meloxicam for 48h after surgery. The protocol requires that animals receive Buprenex and Meloxicam for 48h after surgery. It is stated the PI thought the Buprenex was optional because all the animals recovered uneventfully without apparent pain or distress. The animals were euthanized at the study endpoint. The PI's corrective action plan was to review the protocol with all laboratory members to ensure that the analgesic regimen will be followed.

The IACUC discussed the incident and the PI's corrective action plan at the February 20, 2020 NU IACUC meeting. The Committee accepted the PI's plan and implemented additional requirements. They are listed as the following:

- PI and lab members must complete AALAS course on "Pain Management in Laboratory Animals."
- Provide written documentation that all lab members have read and understand the animal study protocol(s).
- Submit monthly reports to the IACUC summarizing all procedures conducted, analgesic administered and the experimental endpoint.

- Review Rodent Medical Records documentation requirements for surgical procedures with all lab members.
- Maintain all Rodent Medical Records for regular inspection by IACUC and Center for Comparative Medicine (CCM).
- Create a surgical checklist that has been reviewed and signed by all laboratory members.
- Complete Post-Approval Monitoring visit with a focus on surgical procedures conducted by the laboratory.

It is noted that these projects are PHS supported. Based on its assessment of this explanation, OLAW understands that Northwestern University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Northwestern | RESEARCH

Milan Mrksich, PhD
Interim
Vice President for Research

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of Biomedical Engineering
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February 28, 2020

Brent Morse, DVM, DACLAM, Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
OLAW Division of Assurance
National Institutes of Health
Suite 360 MSC 7982
6700B Rockledge Dr., Suite 2500, MSC 6910
Bethesda, MD 20817

Dear Dr. Morse:

I have been informed by the Northwestern University Institutional Animal Care and Use Committee (NU IACUC; Assurance # A3283-01) that a Principal Investigator (PI) reported to the NU IACUC the laboratory's failure to provide animals the full regimen of analgesics after a major survival surgery. These projects are supported by federal funds (5R01NS069777-07; 28 animals and 5R01MH112768-03; 11 animals). The incident report is as follows:

Thirty-nine mice underwent intracranial surgical procedures between November 1, 2019 and November 23, 2019. During the IACUC Office staff satellite visit on December 20, 2019 it was found that the post-operative care was not documented as required on the cage side rodent medical record. After investigation of the matter it was found that the animals only received Meloxicam for 48 hours after the surgery. The protocol requires that the animals receive Buprenex and Meloxicam for 48 hours after surgery. The PI thought that the use of Buprenex was optional because all of the animals recovered uneventfully without apparent pain or distress. The animals were euthanized at the study endpoint.

At the February 20, 2020 NU IACUC meeting, the Committee discussed this incident and reviewed the PI's corrective action plan, which included the following elements:

- Review the protocol with all laboratory members to ensure that the analgesic regimen will be followed.

The Committee accepted the PI's plan to prevent a recurrence of this error, but implemented additional requirements:

- PI and laboratory members must complete AALAS course on "Pain Management in Laboratory Animals."
- Provide written documentation that all laboratory members have read and understand the animal study protocol(s).

- Submit monthly reports to the IACUC summarizing all procedures conducted, analgesic administered and the experimental endpoint.
- Review Rodent Medical Record documentation requirements for surgical procedures with all laboratory members.
- Maintain all Rodent Medical Records for regular inspection by IACUC and Center for Comparative Medicine (CCM).
- Create a surgical checklist that has been reviewed and signed by all laboratory members.
- Complete Post-Approval Monitoring visit with a focus on surgical procedures conducted by the laboratory.

Please let me know if you need any further information.

Sincerely,

(b) (6)

Milan Mrksich, Ph.D.
Interim Vice President for Research
Institutional Official

cc:

(b) (6)

C. Heckman, Ph.D., Chair-IACUC
M. Kozlowski, MSL, CPIA, Director IACUC Office

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 28, 2020 12:04 PM
To: VP Research
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Correspondence from Northwestern University

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: VP Research <VP-Research@northwestern.edu>
Sent: Friday, February 28, 2020 11:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) CJ Heckman <c-heckman@northwestern.edu>; Mandy J Kozlowski <m-kozlowski@northwestern.edu>; (b) (6)
Subject: Correspondence from Northwestern University

Dear Dr. Morse.

Attached please find correspondence from Northwestern University.

(b) (6)

A large rectangular area of the document is completely redacted with a solid grey fill. The redaction covers the main body of the email, likely containing the correspondence mentioned in the subject line.

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