

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
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Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

May 31, 2022

Re: Animal Welfare Assurance #A3283-01 (OLAW Case 3M)

Dr. Milan Mrksich,
Vice President for Research
Northwestern University
750 North Shore Drive, Rubloff
Chicago, IL 60611

Dear Dr. Mrksich,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 6, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Northwestern University (NU). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the NU Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states a Principal Investigator (PI) notified the NU IACUC of 24 mice that underwent sterile saline intraperitoneal (IP) injections on April 4, 2022. These injections were performed to retrain a laboratory member on IP injection techniques. It is stated 10 mice were found dead during animal health checks on April 7th and the remaining 14 animals were humanely euthanized. It was determined that training laboratory members on procedures was not approved in the protocol.

The matter was reviewed by the IACUC on April 21, 2022, and the PI's corrective action plan included retraining the laboratory member under the supervision of a senior laboratory member. The IACUC accepted the PI's plan and implemented the following additional requirements:

- Review the seriousness of the incident with all laboratory members.
- Laboratory members involved in the incident must complete retraining with the CCM Training Office.
- Establish laboratory policy that training and retraining sessions must be conducted by the CCM Training Office.
- Restrict laboratory personnel permissions to order animals and implement a verification process for animal orders.
- Remind all laboratory members to contact a veterinarian to review mortalities and conduct a necropsy.

It is noted that this research is supported by PHS funding and charges related to the unapproved procedures will not be charged to the grant. Based on its assessment of this explanation, OLAW understands that the 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.

Page 2 – Dr. Mrksich May 31, 2022 OLAW Case A3283-3M

Sincerely,

Jacquelyn Digitally signed by Jacquelyn T. Tubbs -S Date: 2022.05.31 13:37:30 -04'00'

Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

May 6, 2022

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 that an incident involving animals occurred. This project is supported by federal funds (1R01MH114923-01A1). The incident report is as follows:

Incident Description:

The Principal Investigator (PI) reported that twenty-four mice underwent sterile saline intraperitoneal injection procedures on April 4, 2022. The procedure was conducted to retrain a laboratory member on IP injection techniques because it was over one year since initial training. During CCM animal health checks on April 7, 2022, 10 animals were found deceased. The remaining fourteen animals were humanely euthanized. After review of the matter, it was found that training laboratory members on procedures was not approved in the protocol.

At the April 21, 2022 NU IACUC meeting, the Committee discussed this incident and reviewed the PI's corrective action plan, which included the following elements:

• Retrain laboratory member under the supervision of a senior laboratory member.

The Committee accepted the PI's plan, but implemented the following additional requirements:

- Review the seriousness of the incident with all laboratory members.
- Laboratory members involved in the incident must complete retraining with the CCM Training Office.
- Establish laboratory policy that training and retraining sessions must be conducted by the CCM Training Office.
- Restrict laboratory personnel permissions to order animals and implement a verification process for animal orders.

 Remind all laboratory members to contact a veterinarian to review mortalities and conduct a necropsy.

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Charges related to these unapproved procedures will not be charged to the NIH grant.

Please let me know if you need any further information.

(b) (6)

Sincerely,

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

cc: C. Heckman, Ph.D., Chair - IACUC

Wolff, Axel (NIH/OD) [E] OLAW Division of Compliance Oversight (NIH/OD) From: Monday, May 9, 2022 7:21 AM Sent: (b) (6) To: OLAW Division of Compliance Oversight (NIH/OD) Cc: RE: Northwestern Report to OLAW Subject: (b) (6) We will send a response soon. Thank you for this report, Axel Wolff, M.S., D.V.M. Deputy Director, OLAW From: Sent: Saturday, May 7, 2022 7:37 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> (b) (6) Cc: Milan Mrksich <milan.mrksich@northwestern.edu>; CJ Heckman <c-heckman@northwestern.edu> (b)(6)Subject: [EXTERNAL] Northwestern Report to OLAW Dear Division of Compliance Oversight, Please find correspondence from Milan Mrksich, Vice President for Research, Northwestern University. Thanks, (b) (6)