



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) 480-3387

September 14, 2021

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

Dr. Milan Mrksich,
Vice President for Research
Northwestern University
750 North Shore Drive, (b) (4)
Chicago, IL 60611

Dear Dr. Mrksich,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 22, 2021 final letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. This letter is preceded by a preliminary e-mailed report to OLAW provided on May 25, 2021. According to the information provided, OLAW understands that during a routine post-approval monitoring procedure, it was found that on April 21, 2021, eight mice underwent Azlet pump replacement surgery. The surgery was not approved on the protocol and proper aseptic technique involving removal of fur from surgical site as required by IACUC guidelines was not performed. On April 26, 2021, one animal was found deceased, one animal humanely euthanized and the six remaining animals were transferred to the appropriate study where pump replacement surgery was approved. The study was supported by PHS funding.

As a corrective measure, the seriousness of incident was reviewed with laboratory members, all lab members must verify the procedure and protocol number prior to implementation of activities. In addition, a laboratory member must be designated as responsible for ensuring all protocols are followed and all laboratory personnel conducting surgery must take the hands-on rodent survival surgery course. Post-approval monitoring of surgical procedures will also be implemented and conducted.

OLAW appreciates the prompt consideration of this matter by Northwestern University which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence.

We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact

July 22, 2021

research@northwestern.edu
Office 847. 491. 3485

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Animal Welfare Program Specialist
Division of Assurances
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive, Suite 2500, MSC-6910
Bethesda, Maryland 20892-6910
Nicole.Lukovsky@NIH.gov

Re: Final report for preliminary notification sent on 5/26/21

Dear Dr. Lukovsky-Akhsanov:

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 PHS funds. The incident report is as follows:

Incident Descriptions:

- During a routine PAM visit and review of cage level documentation, it was found that eight mice underwent Azlet pump replacement surgery on April 21, 2021. The pump replacement procedure was not approved on the protocol the animals were assigned and the fur was not removed from the surgical site as required by IACUC Guidelines for Rodent Survival Surgery. On April 26, 2021, one animal was found deceased due to post-surgical complications and, through veterinary consultation, one animal was humanely euthanized because the pump size was too large based on the animal's body weight. The remaining six animals were transferred to the appropriate study where the pump replacement surgery was approved.

At the May 20, 2021 NU IACUC meeting, the Committee discussed this incident and reviewed the PI's corrective action plan, which included the following elements:

- Review the seriousness of the incident with all laboratory members at a laboratory meeting.
- Instruct all laboratory members to verify the procedure and protocol number prior to implementation of procedures.

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

- Designate a laboratory member responsible for ensuring all protocols are followed.
- All laboratory personnel conducting surgery must take the hands-on rodent survival surgery course.

Additional measures implemented includes a PAM observation of the surgical procedures conducted by the laboratory.

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

Please let me know if you need any further information.

Sincerely,

(b) (6)

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

cc:

(b) (6)

C. Heckman, Chair - IACUC

(b) (6)

May 25, 2021

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 two separate incidents involving animals occurred. Both projects are supported by federal funds. The incident report is as follows:

Incident Descriptions:

- Eight mice underwent Azlet pump replacement surgery on April 21, 2021. The pump replacement procedure was not approved on the protocol the animals were assigned and the fur was not removed from the surgical site as required by IACUC Guidelines for Rodent Survival Surgery. On April 26, 2021, one animal was found deceased, one was humanely euthanized and six animals remain on study.
- Fifteen mice underwent pulmonary arterial hypertension procedures using a hypoxia environmental chamber on April 4, 2021 and April 12, 2021. The oxygen sensor failed leading to fifteen mortalities.

At the May 20, 2021 NU IACUC meeting, the Committee discussed these incidents and reviewed the PI's corrective action plan, which included the following elements:

- Review the seriousness of the incident with all laboratory members at a laboratory meeting.
- Instruct all laboratory members to verify the procedure and protocol number prior to implementation of procedures.
- Replace oxygen sensor at least once every two years per manufacturer guidance.

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

- Designate a laboratory member responsible for ensuring all protocols are followed and oversight for chamber maintenance.
- All laboratory personnel conducting surgery must take the hands-on rodent survival surgery course.
- Install an immediate notification alarm for the hypoxia chamber that alerts laboratory members when the oxygen level decrease.

- Consult with colleagues using similar environmental chambers and schedule training with chamber manufacturer on appropriate use of the chambers.

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

Please let me know if you need any further information.

Sincerely,

(b) (6)

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

cc:

(b) (6)

C. Heckman, Chair, IACUC

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 28, 2021 6:55 AM
To: VP Research
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Correspondence from Northwestern University 210525_002

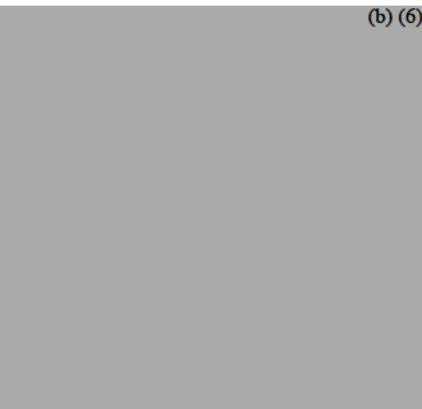
Thank you. We will send a response soon.

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

From: VP Research <VP-Research@northwestern.edu>
Sent: Wednesday, May 26, 2021 10:31 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: CJ Heckman <c-heckman@northwestern.edu>; (b) (6)
Subject: Correspondence from Northwestern University 210525_002

Dear Dr. Morse,

Attached please find correspondence from Milan Mrksich, Vice President for Research, Northwestern University.



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