



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 23, 2021

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

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) receipt of your September 17, 2021 letter in response to OLAW's revised September 14, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. According to the information provided, OLAW understands that during routine veterinary health checks, 13 mice were found to have sustained ocular injury as a result of the unapproved blood collection procedures and were humanely euthanized as a result. The laboratory member completed training on May 27, 2021 with the Center for Comparative Medicine training office.

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

September 17, 2021

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: OLAW Case A3283-3G

Dear Dr. Lukovsky-Akhsanov:

Thank you for your review of this matter and request for clarification. Please see the response below to the clarification requested:

1. Please provide information regarding direct animal welfare concerns related to the noncompliance which resulted in euthanasia of 13 animals.

Response: During routine veterinary health checks, thirteen animals were found with ocular injury from unapproved retro-orbital blood collect procedures. After consultation with the veterinarian, the animals were humanely euthanized. The laboratory member involved completed retraining on May 27, 2021 with the Center for Comparative Medicine (CCM) training office.

Again, thank you for your review of this matter. Please let me know if you need further information.

Sincerely,

(b) (6)

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

cc:

(b) (6)

C. Heckman, Chair - IACUC

(b) (6)



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Facsimile: (301) 480-3387

September 14, 2021

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

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 May 25, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. According to the information provided, OLAW understands that on May 1, 2021, the Principal Investigator discovered 33 mice underwent a high fat diet for 12 weeks followed by blood collection procedures. The procedures were not approved on the protocol to which the animals were assigned and 13 of the mice were humanely euthanized with the remaining 20 mice transferred to the correct protocol. The studies were supported by federal funding.

As a corrective measure, a review to ensure animals are assigned to correct protocols and verification of protocol numbers was implemented, review of cage card design for ease of protocol verification, maintaining printed copies of the protocol in the lab and retraining lab members on approved protocol procedures were required by the IACUC. Charges related to unapproved procedures will not be charged to the grant.

OLAW appreciates the prompt consideration of this matter by Northwestern University which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests the following information:

- Please provide information regarding direct animal welfare concerns related to the noncompliance which resulted in euthanasia of 13 animals.

We look forward to your responses to the to the additional information request by **October 15, 2021**. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole
L. Lukovsky-akhsanov -S
Date: 2021.09.14 11:23:36
-04'00'

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

CC: IACUC contact

Northwestern | RESEARCH

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

Northwestern University
Office for Research
Rebecca Crown Center
633 Clark Street
Evanston, Illinois 60208

research@northwestern.edu
Office 847. 491. 3485

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. The project is supported by federal funds. The incident report is as follows:

Incident Descriptions:

On May 1, 2021, the Principal Investigator discovered that thirty-three mice underwent a high fat diet for twelve weeks followed by blood collection procedures. The procedures were not approved on the protocol the animals were assigned. Thirteen of the mice were humanely euthanized and the remaining twenty mice were transferred to the correct protocol.

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 importance of ensuring that animals are assigned to the appropriate protocols prior to implementing procedures.
- Update laboratory checklist to include verification of the protocol numbers before conducting procedures.
- Review cage card design with all laboratory members so they understand how to locate the protocol number.
- Maintain printed protocol copies in the laboratory to avoid confusion on protocol numbers and approved procedures.
- Retrain laboratory members on approved protocol procedures.

The Committee agreed that the PI's plan was adequate to prevent future incidents.

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 6:56 AM
To: VP Research
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Correspondence from Northwestern University 210525_003

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)
(b) (6)
Subject: Correspondence from Northwestern University 210525_003

Dear Dr. Morse,

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

(b) (6)



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