



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 9, 2021

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

Dr. Milan Mrksich,
Vice President for Research
Northwestern University
750 North Shore Drive, (b) (6)
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 on April 4, 2021 and April 12, 2021, 15 mice underwent pulmonary arterial hypertension procedures using a hypoxia environmental chamber whereupon the oxygen sensor failed leading for mortality of all 15 animals. The project is supported by PHS funding.

As a corrective measure, the seriousness of incident was reviewed with laboratory members including chamber maintenance. The oxygen sensor must be replaced at least once every two years per manufacturer guidelines and a laboratory member must be designated as responsible for ensuring all protocols are followed including chamber maintenance. Installation of an immediate notification alarm for the hypoxia chamber that alerts lab members when oxygen levels decrease must be completed. In addition, consultation with colleagues using similar chambers and scheduling training with the manufacturer on appropriate use of chambers must be completed. Monthly post-approval monitoring record review of documentation will be conducted along with visits to the environmental chamber housing rooms.

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,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S
Date: 2021.09.09 16:25:42
+04'00'

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:

- 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 and the importance of chamber maintenance.
- 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 oversight for chamber maintenance.
- 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.

Additional measures implemented includes routine PAM visits to the environmental chamber housing rooms and monthly reviews environmental chamber monitoring documentation records for completeness.

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)