

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF

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

August 6, 2021

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 Facsimile: (301) 480-3387

Re: Animal Welfare Assurance #A3456-01 [OLAW Case 9V] UMN IACUC #38514A

Dr. Michael J. Oakes Interim Vice President for Research Institutional Official University of Minnesota ^{(b) (4)}Johnston Hall - 101 Pleasant St., SE Minneapolis, MN 55455

Dear Dr. Oakes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 22, 2021 letter in response to OLAW's July 13, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. According to the information provided, OLAW understands that no health inventions were required, and no animal welfare concerns occurred due to the noncompliance.

OLAW appreciates the prompt consideration of this matter by University of Minnesota 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,

Nicole L. Lukovskyakhsanov -S Date: 2021.08.06 13:46:22 -04'00'

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

CC: IACUC contact

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

Mayo Mail Code 79 D-528 Mayo Memorial Building 420 Delaware St. SE Minneapolis, MN 55455 Phone: 612-626-2126 Fax: 612-626-6061 jacuc@umn.edu www.research.umn.edu/jacuc

July 22, 2021

- TO: Axel Wolff, DVM Office of Laboratory Animal Welfare National Institutes of Health RKL1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982
- RE: University of Minnesota Animal Care Program D16-00288 (A-3456-01) NIH Grant Number: R01 AI124512 UMN IACUC #38514A

Dear Dr. Wolff,

Thank you for your response to our report of non-compliance of an IACUC approved, NIH funded study involving mice (UMN IACUC #38514A). We understand that you are requesting the following additional information:

• Please provide information regarding any direct animal welfare concerns related to the noncompliance including any required interventions to ensure animal health.

In response, there were no direct animal welfare concerns related to the noncompliance and no health interventions were required.

Sincerely.

(b) (6)

J. Michael Oakes, Ph.D. Interim Vice President for Research Institutional Official, University of Minnesota 101 Pleasant Street, S.E. Minneapolis, MN 55455

CC: Richard Bianco, Chair, IACUC Lynn Collura Impelluso, Institutional Veterinarian



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July 13, 2021

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 Facsimile: (301) 480-3387

Re: Animal Welfare Assurance #A3456-01 [OLAW Case 9V] UMN IACUC #38514A

Dr. Michael J. Oakes Interim Vice President for Research Institutional Official University of Minnesota ^{(b) (4)} Johnston Hall - 101 Pleasant St., SE Minneapolis, MN 5545

Dear Dr. Oakes

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 15, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. According to the information provided, OLAW understands that during a post-approval monitoring inspection the use of expired anesthesia occurred in 70 mice from January 2021 to present. This study was supported by PHS funding.

As a corrective measure, the principal investigator (PI) stated the expired anesthetic was discontinued immediately and the laboratory purchased a new bottle for use. A lab calendar has a scheduled reminder every six months to check expiration dates for all chemical used in animals.

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

 Please provide information regarding any direct animal welfare concerns related to the noncompliance including any required interventions to ensure animal health.

We look forward to your responses to the to the additional information request by **August 13, 2021**. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky Digitally signed by Nicole L. Lukovsky-akhsanov -S akhsanov -S 04/00'

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

CC: IACUC contact

A3454-91

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

Mayo Mail Code 79 D-528 Mayo Memorial Building 420 Delaware St. SE Minneapolis, MN 55455 Phone: 612-626-2126 Fax: 612-626-6061 iacuc@um.edu www.research.umn.edu/jacuc

June 15, 2021

- TO: Axel Wolff, DVM Office of Laboratory Animal Welfare National Institutes of Health RKL1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982
- RE: University of Minnesota Animal Care Program D16-00288 (A-3456-01) NIH Grant#: R01 AI124512 UMN IACUC #38514A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of non-compliance of an IACUC approved, NIH funded study involving mice. The basis of this report results from a post approval monitoring inspection. The report outlined the use of expired anesthetic in research animals which occurred from January 2021 to present involving 70 mice.

We want to inform you that we consider this matter closed. A response was received from the PI stating that use of the expired anesthetic was discontinued immediately and the laboratory has purchased a new bottle of anesthetic for subsequent experiments (expiration September 2025). Additionally, a recurring lab calendar reminder has been scheduled for every six months to check expiration dates for all chemicals used in animals.

Sincerely.

(b) (6)

J. Michael Oakes, Ph.D. Interim Vice President for Research Institutional Official, University of Minnesota 101 Pleasant Street, S.E. Minneapolis, MN 55455

CC: Richard Bianco, Chair, IACUC Lynn Collura Impelluso, Institutional Veterinarian

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)		
Sent:	Wednesday, June 16, 2021 9:42 AM		
То:	(b) (б)		
Cc:	OLAW Division of Compliance Oversight (NIH/OD)		
Subject:	RE: Report of Non-compliance		

Thank you for this report. We will send a response soon. Axel Wolff

From: (b) (6)

Sent: Wednesday, June 16, 2021 9:16 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Lynn Impelluso <impell@umn.edu>; Richard Bianco <bianc001@umn.edu>; Michael Oakes <oakes007@umn.edu> Subject: Report of Non-compliance

Dear Dr. Wolff,

On behalf of Interim Vice President Oakes, attached please find a report of non-compliance. Please let me know if you have any questions.

Thank you,

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