



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

October 4, 2021

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 9W]
UMN IACUC #38896A

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 September 29, 2021 letter in response to OLAW's September 15, 2021 request for information regarding 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 the IACUC requires the principal investigator and every individual listed as staff on the protocol to complete mandatory training including information about protocol review, approval procedures and protocol compliance and amendments. Additionally, all labs are subject to Post Approval Monitoring inspections at least every other year. For this instance of non-compliance, responsible research personnel have been retrained on protocol compliance and confirmed understanding of its importance to IACUC staff.

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

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@umn.edu
www.research.umn.edu/iacuc

September 29, 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: R01HL-155993
UMN IACUC #38896A

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 #38896A). We understand that you are requesting the following additional information:

- Please provide details regarding any training conducted for research personnel on the topic of protocol compliance.

In response, the UMN IACUC requires the PI and every person listed as staff on the protocol to complete the Animal Use Tutorial. This training includes information about the protocol review and approval process and also covers protocol compliance and amendments. This training is mandatory and the protocol is not approved until all staff listed on the protocol have completed it. Additionally, all labs are subject to Post Approval Monitoring inspections at least every other year where the topic of protocol compliance is covered by IACUC staff. Finally, research personnel responsible for this instance of noncompliance have been retrained on protocol compliance and have confirmed their understanding of its importance to IACUC staff.

Thank you again for your response and please let us know if you have further questions.

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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September 15, 2021

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 9W]
UMN IACUC #38896A

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 August 2, 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 on May 18, 2021, six mice underwent surgery but did not receive analgesia at least two hours to the surgery as stated in the protocol but instead received analgesia one hour prior to the procedure which would not have allotted appropriate analgesic coverage. This study was supported by PHS funding.

As a corrective measure, the Principal Investigator indicated that the extended-release analgesic will be given at least two hours prior to surgery as required. A review of surgery and post-operative records revealed animals were checked daily and assessed for pain and distress each day for three day post-operatively and no pain or distressed was observed by staff.

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 details regarding any training conducted for research personnel on the topic of protocol compliance.

We look forward to your responses to the to the additional information request by **October 15, 2021** to Nicole.Lukovsky@NIH.gov 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

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

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420 Delaware St. SE
Minneapolis, MN 55455
Phone: 612-626-2126
Fax: 612-626-6061
iacuc@umn.edu
www.research.umn.edu/iacuc

August 2, 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: R01HL-155993
UMN IACUC #38896A

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 surgical inspection. The report outlined that six mice undergoing surgery did not receive the required analgesic at least two hours prior to surgery as described in the protocol, but instead were given this analgesic one hour prior to the procedure which would not have allotted appropriate analgesic coverage. This deviation in protocol occurred on May 18, 2021.

We want to inform you that we consider this matter closed. A response was received from the PI indicating that the extended release analgesic will be given at least two hours prior to surgery as required to ensure analgesic coverage. Additionally, according to the laboratory and review of surgical and post-operative records for these animals, animals were checked daily and specifically assessed for pain and distress each day for three days after surgery. No pain or distress were observed by staff.

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, August 11, 2021 7:27 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-Compliance

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Monday, August 9, 2021 4:21 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Richard Bianco <bianc001@umn.edu>; Lynn Impelluso <impell@umn.edu>
Subject: Report of Non-Compliance

Dear Dr. Wolff,
On behalf of interim VPR Michael Oakes, attached please find a report of non-compliance.
Thank you and let me know if you have any questions.
(b) (6)

(b) (6)