



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

May 19, 2022

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 10D]
UMN IACUC #38630A

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 May 2, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Minnesota. According to the information provided, OLAW understands that 12 mice underwent an approved skin graft procedure but were not administered an analgesic as outlined in the protocol. The incident was discovered during a routine post-approval surgical inspection. The mice were not noted to be overtly painful by laboratory or animal care staff and no interventions were required. The animals involved in this incident were supported by NIH funding.

Corrective and preventive measures included counseling of the principal investigator who has confirmed that going forward all animals will receive pre-operative analgesic as approved in the protocol, and that this administration will be recorded in the animals' surgical records. The laboratory has also updated their instructional SOPs and surgical record keeping forms to include the requirement for analgesic administration.

OLAW appreciates the consideration of this matter by the University of Minnesota which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M. Engel
-S
Date: 2022.05.19 11:21:39 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
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
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iacuc@umn.edu
www.research.umn.edu/iacuc

May 2, 2022

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: 5U01AI132904-06
UMN IACUC #38630A

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 mice that underwent a skin graft procedure were not administered an analgesic as outlined in the protocol. This deviation in protocol occurred on April 7, 2022 and involved twelve mice. The mice were not noted to be overtly painful by laboratory or animal care staff and no interventions were required.

We want to inform you that we consider this matter closed. The PI has confirmed that going forward, all animals will receive pre-operative sustained-release analgesic as approved in the IACUC protocol, and that this administration will be recorded in the animals' surgical records. The laboratory has updated their instructional SOPs and surgical record keeping forms to include the requirement for analgesic administration for this procedure. The IACUC will monitor ongoing compliance through semi-annual surgical inspections and annual post approval monitoring.

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, May 4, 2022 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Report of Non-compliance

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

From: (b) (6)
Sent: Tuesday, May 3, 2022 9:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Richard Bianco <bianc001@umn.edu>; Lynn Impelluso <impell@umn.edu>
Subject: [EXTERNAL] Report of Non-compliance

Dear Dr. Wolff,

Attached please find a letter with a report of non-compliance. Please let me know if you have any questions.

Thanks,

(b) (6)

(b) (6)

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