



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

August 25, 2022

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 10G]
UMN IACUC # 37610A

Dr. Frances Lawrenz
Interim Vice President for Research
Institutional Official
University of Minnesota
101 Pleasant St., SE
Minneapolis, MN 55455

Dear Dr. Lawrenz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 19, 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 66 mice undergoing an osmotic minipump implantation procedure were not administered an analgesic as outlined in the approved protocol. The protocol states that the animals would receive pre- and post-operative meloxicam. The animals were monitored daily for three days post-surgery by laboratory staff. None of the mice were noted to be overtly painful and no post-operative medications were given. The issue was discovered during a post-approval monitoring inspection. The mice involved in this incident were supported by NIH funds.

Several corrective and preventative measures were enacted. The principal investigator (PI) has confirmed that all mice will receive post-operative analgesia as outlined in the protocol going forward, and that all doses will be recorded in the animals' surgical and post-operative records. The laboratory has adopted IACUC-supplied surgical and post-operative record keeping templates that include the requirement for analgesic administration. The IACUC will also monitor ongoing compliance through semiannual surgical inspections and annual post-approval monitoring.

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: 2022.08.25 12:43:18 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

CC: IACUC contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, August 25, 2022 3:09 PM
To: lawrenz@umn.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); iacuc@umn.edu; (b) (6)
Subject: OLAW Case A3456-10G
Attachments: A3456-10G.pdf

Good afternoon Dr. Lawrenz,

Attached please find Dr. Engel's response to OLAW Case A3456-10G. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

A3456-106

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*

August 19, 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: R01DA007304
UMN IACUC #37610A

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 that on dates ranging from 3/23/22 to 7/25/22, a total of 66 mice undergoing the osmotic minipump implantation procedure were not administered an analgesic as outlined in the approved protocol. The protocol states that animals undergoing this procedure will be administered meloxicam once pre-operatively and then every 24 hours for 72 hours. Animals were monitored daily for three days post-surgery by laboratory staff, and none of the mice were noted to be overtly painful and no interventions were required.

We want to inform you that we consider this matter closed. The PI has confirmed that, going forward, all mice will receive the analgesic pre-operatively and for the full 72 hours as outlined in the protocol, and that all doses will be recorded in the animals' surgical and post-operative records. The laboratory has adopted IACUC-supplied surgical and post-operative record keeping templates that include the requirement for analgesic administration. The IACUC will monitor ongoing compliance through semi-annual surgical inspections and annual post approval monitoring.

Sincerely,

(b) (6)


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

CC: Erin Dickerson, Chair, IACUC
Lynn Collura Impelluso, Institutional Veterinarian

McCoy, Devora (NIH/OD) [E]

From: [REDACTED] (b) (6)
Sent: Friday, August 19, 2022 2:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: [REDACTED] (b) (6); Lynn Impelluso; Frances Lawrenz; Erin Dickerson
Subject: [EXTERNAL] UMN IACUC #37610A
Attachments: UMN IACUC 37610A.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Wolff,
Attached please find a report of non-compliance. Please let me know if you have any questions.
Thank you,

[REDACTED] (b) (6)

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McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 19, 2022 4:10 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] UMN IACUC #37610A

Good afternoon (b) (6)

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Friday, August 19, 2022 2:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Lynn Impelluso <impell@umn.edu>; Frances Lawrenz <lawrenz@umn.edu>; Erin Dickerson <edickers@umn.edu>
Subject: [EXTERNAL] UMN IACUC #37610A

Dear Dr. Wolff,
Attached please find a report of non-compliance. Please let me know if you have any questions.
Thank you,

(b) (6)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.
