



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

February 12, 2025

Re: Animal Welfare Assurance
A3456-01 [OLAW Case 11M]

Shashank Priya, Ph.D.
Vice President for Research and Innovation
University of Minnesota – Main Campus
(b) (4) - 101 Pleasant St. SE
Minneapolis, MN 55455

Dear Dr. Priya,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 31, 2025, 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 two rats did not receive the IACUC-approved analgesic regimen for their cranial electrode implantation surgeries. The approved regimen included preoperative extended-release buprenorphine, lidocaine, and carprofen, and a second dose of carprofen 24 hours later. One rat received the buprenorphine postoperatively instead of preoperatively. The second rat did not receive buprenorphine or the second dose of carprofen. The animals did not show any signs of pain or distress when monitored for 3 days after the procedures. The mistakes were found during a post-approval monitoring review of surgical records. The rats involved in these incidents were supported by NIH funds.

Corrective and preventative measures included retraining laboratory staff members to ensure that all analgesics are administered as approved and are clearly documented in the surgical and postoperative records. All surgeons in the laboratory will re-read the relevant IACUC protocols to ensure that they are familiar with approved analgesic requirements. Future compliance will be monitored during semiannual inspections and annual post-approval monitoring of the laboratory.

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, it seems 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: 2025.02.12 14:23:49 -05'00'

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

cc: IACUC Contact

*Twin Cities Campus**Institutional Animal Care and Use Committee (IACUC) Office*

(b) (4)
(b) (4) *McNamara Ctr*
200 Oak St SE (b) (4)
Minneapolis, MN 55455
(b) (6)
iacuc@umn.edu
www.research.umn.edu/units/iacuc

January 31, 2025

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: 5R01MH123634
UMN IACUC #40918A

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 rats. The basis of this report results from a post-approval monitoring inspection. Review of surgical records during this inspection indicated that on July 23rd and July 30th, 2024, two rats (one each date) were documented as not receiving the analgesic regimen approved in the IACUC protocol. The approved analgesic regimen for the cranial electrode implantation surgery includes multi-modal analgesia with extended-release buprenorphine, carprofen, and lidocaine given pre-operatively and an additional dose of carprofen given 24 hours post-operatively. For the July 23rd surgery, the buprenorphine dose was administered post-operatively instead of pre-operatively. For the July 30th surgery, neither buprenorphine nor the 24-hour post-operative dose of carprofen were administered, according to the records.

This noncompliance had the potential to result in the rats not receiving adequate analgesia for their surgical procedure. Lab staff monitored animals daily for three days post-surgery in addition to routine daily health checks conducted by vivarium staff, and no signs of pain or distress were detected in these animals as a result of this noncompliance.

We want to inform you that we believe appropriate steps have been taken to prevent recurrence and that we consider this matter closed. The lab has confirmed that they will retrain staff on ensuring that all analgesics are administered as approved and are clearly documented in the surgical and post-operative records. All surgeons in the lab will reread the IACUC protocols that they work on to ensure that they are familiar with the approved analgesic requirements. Future compliance will be monitored by semi-annual surgical inspections and annual post-approval monitoring.

Sincerely,

(b) (6)

Shashank Priya, Ph.D.
Vice President for Research and Innovation
Institutional Official, University of Minnesota
200 Oak Street, S.E.
Minneapolis, MN 55455

CC: Erin Dickerson, Chair, IACUC
Nate Koewler, Institutional Veterinarian
AAALAC

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 7, 2025 7:53 AM
To: (b) (6)
Cc: (b) (6); Nate Koewler; Erin Dickerson; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] OLAW non-compliance report for NIH Grant 5R01MH123634

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11M**. We will send an official response soon.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

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From: (b) (6)
Sent: Thursday, February 6, 2025 6:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) <[redacted]> accredit@aaalac.org; Nate Koewler <koew0004@umn.edu>; Erin Dickerson <edickers@umn.edu>
Subject: [EXTERNAL] OLAW non-compliance report for NIH Grant 5R01MH123634

Dear Dr. Wolff,

Attached please find the non-compliance letter sent on behalf of VP Priya.

Kindly,

(b) (6)

(b) (6)