



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

April 10, 2024,

Re: Animal Welfare Assurance
#A3456-01 (OLAW Case 10Y)

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

Dear Dr. Priya,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated March 22, 2024, regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. The issue involved 6 mice that were part of a PHS-funded activity. This letter had not been preceded by a preliminary report to OLAW.

Based on your letter, OLAW understands that the incident was identified on a post-approval monitoring inspection where it was determined that on December 12 and 22, 2023, expired buprenorphine had been given to the animals. The expiration date of the drug was December 4, 2023, and no adverse effects were noted in the affected mice. This laboratory had not yet been visited by the Institutional Animal Care and Use Committee (IACUC), so the corrective measures for expired drugs as outlined in your November 17, 2023 letter to this Office had not yet been fully implemented. The laboratory has properly disposed of the expired drug and has ordered new vials.

OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and at this time find no cause for further action by this Office. We look forward to the continued implementation and assessment of your corrective plan and ask that you contact us if the corrective actions are not carried out as described.

Sincerely,

4/10/2024

X Nicolette Petervary

Nicolette Petervary
Director, Division of Policy and Education
Signed by: Nicolette A. Petervary -A

Nicolette Petervary, VMD, MS, DACAW
Director, Division of Policy and Education
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3456-104

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

March 22, 2024

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: 1RF1NS126044
UMN IACUC #39800A

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. A review of the lab's surgical and controlled substances records indicated that between 12/12/23 and 12/22/23, a vial of buprenorphine that had expired on 12/4/23 was used as an analgesic for surgical procedures on 6 mice.

No adverse effects on the mice were noted as a result of the use of the expired drug.

We want to inform you that we consider this matter closed. The lab has properly disposed of the expired drug and ordered new stock. We also wish to address how this incident relates to our letter of 11/17/23, which was sent in response to cases 10S and 10T. In that letter, we described a plan to address recurrent issues with the use of expired anesthetics or analgesics. The plan included a new requirement for labs to use color-coded stickers to promote easier visual identification of expiration dates. While all investigators were informed of this requirement via email on 11/17/23, in person delivery of stickers and instruction on their use have been taking place on a rolling basis as labs are visited for their semi-annual or post approval monitoring inspections. The lab involved in this incident had not yet been visited by the IACUC or received stickers at the time of this non-compliance. Therefore, we continue to believe that the plan outlined in our 11/17/23 letter will ultimately be effective in preventing use of expired drugs.

Sincerely,

(b) (6)

Shashank Priya, Ph.D.
Vice President for Research and Innovation
Institutional Official, University of Minnesota
101 Pleasant 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, March 29, 2024 8:03 AM
To: (b) (6)
Cc: Nate Koewler; Erin Dickerson; (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Non-Compliance Reports

Good morning,

Thank you for providing these two reports, which have been assigned as OLAW cases **A3456-10X** (IACUC #41198A) and **A3456-10Y** (IACUC #39800A). We will send official responses 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, March 28, 2024 10:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@aaalac.org; Nate Koewler <koew0004@umn.edu>; Erin Dickerson <edickers@umn.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Non-Compliance Reports

Dear Dr. Wolff,

On behalf of VPR Shashank Priya, please find the attached reports of non-compliance. Please let me know if you have any questions.

Thank you.

(b) (6)

(b) (6)

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