



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

September 9, 2024

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

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 August 16, 2024 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 recently expired analgesic was given to three mice post-operatively.

The corrective actions consisted of disposing of the expired drug and obtaining new stock. A program wide plan to prevent use of expired drugs is still in the process of implementation and involves use of color-coded stickers. The laboratory involved has received the stickers and instruction on their use.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Acting Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3456-11E

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

(b) (4)
420 Delaware St. SE
Minneapolis, MN 55455

(b) (6)
iacuc@umn.edu
www.research.umn.edu/iacuc

August 16, 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: R01CA263777
UMN IACUC # 39630A

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 records indicated that on June 7, 2024, carprofen that had expired in April 2024 was used as an analgesic for three mice undergoing an IACUC approved surgical procedure.

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 obtained 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 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 only recently resumed survival surgeries after a hiatus, and therefore had not yet received stickers between the time when the requirement began and the time of this non-compliance. The PI has now been provided with labeling stickers and instructed on their use. 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
200 Oak Street, SE, 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: Thursday, September 5, 2024 11:15 AM
To: (b) (6)
Cc: Nate Koewler; Erin Dickerson; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] OLAW non-compliance report for NIH Grant R01CA263777

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11E**. 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, September 5, 2024 11:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6); accredit@aaalac.org; Nate Koewler <koew0004@umn.edu>; Erin Dickerson <edickers@umn.edu>
Subject: [EXTERNAL] OLAW non-compliance report for NIH Grant R01CA263777

Dear Dr. Wolff,

On behalf of VPR Priya, please find the attached non-compliance letter.

Best,

(b) (6)

(b) (6)