



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

December 23, 2024

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

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 December 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. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this office understands that the University of Minnesota Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to the use of expired drugs in animals. The final report states a review of a laboratory's euthanasia records and drug stocks revealed on October 15th and 22nd of this year, a bottle of xylazine that expired in August 2024 had been used for euthanasia procedures for 16 mice. It is stated no adverse effects were observed from the use of the expired drug.

In response to the finding, the laboratory properly disposed of the expired drug and obtained new stock. Your letter references two closed cases that described a plan to address recurrent issues with the use of expired anesthetics and analgesics. It is stated the plan included a mandate for labs to use color-coded stickers to promote visual identification of expiration dates. Per the report, all investigators were notified of this requirement on November 17, 2023 and delivery of stickers with instructions on their use have been occurring on a rolling basis as labs are visited during scheduled inspections. It is understood the lab associated with this incident had not yet received stickers in October 2024. In response to the incident, the investigator and research staff have now received labeling stickers, including instructions for use.

It is noted the research project is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Minnesota has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

JACQUELYN T.
TUBBS -S

Digitally signed by JACQUELYN
T. TUBBS -S
Date: 2024.12.23 13:12:07 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3456-11K

UNIVERSITY OF MINNESOTA

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

December 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: R01DK132849
UMN IACUC #40634A

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 euthanasia records and drug stocks indicated that on October 15 and October 22, 2024, a bottle of xylazine that had expired in August 2024 was used for euthanasia procedures for a total of 16 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 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 regularly scheduled inspections. The lab involved in this incident had not yet received stickers in October 2024, at the time of this non-compliance. The PI and lab staff have 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, S.E.
Minneapolis, MN 55455

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

Driven to DiscoverSM

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 18, 2024 10:01 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: R01DK132849

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11K**. 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: Wednesday, December 18, 2024 9:46 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: R01DK132849

Dear Dr. Wolff,

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

Best,

(b) (6)

(b) (6)