



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

October 25, 2024

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

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 October 23, 2024, letter reporting an occurrence 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 an incident of noncompliance occurred with respect to the use of expired drugs for the conduct of animal-related activities on an IACUC-approved protocol. The final report states that during a post-approval monitoring visit, it was discovered that on April 2, and April 9, 2024, an expired anesthetic was used for the perfusion of 9 mice. There were no adverse events noted regarding the mice.

Per the final report, the lab has properly disposed of the expired drug and obtained a new stock. Additionally, in the final report the IACUC addressed how this incident relates to previous similar incidents, where 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 received stickers at the time of this non-compliance. The Principal Investigator has now been provided with labeling stickers and instructed on their use. With this, the IACUC determined the corrective action plan was adequate in preventing use of expired drugs, and no further action was required.

It is noted that this study is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that University of Minnesota has implemented measures to correct and prevent recurrence of this problem. OLAW recommends retraining of any additional lab staff that may have access to animal housing room. We appreciate being informed of this matter and find no cause for further action by this Office.

Sincerely,

Angelina M.  
Williams -S

Angelina Williams, DVM, MPH, DACLAM  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare

Digitally signed by Angelina M.  
Williams -S  
Date: 2024.10.25 10:03:20  
-04'00'

cc: IACUC Contact

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

(b) (4)

200 Oak St SE (b) (4)  
Minneapolis, MN 55455

(b) (6)

[iacuc@umn.edu](mailto:iacuc@umn.edu)[www.research.umn.edu/units/iacuc](http://www.research.umn.edu/units/iacuc)

October 23, 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: 1R21 NS117978  
UMN IACUC # 41626A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of non-compliance on 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 anesthetic records and drug stocks indicated that on April 2 and April 9, 2024, xylazine that had expired in March 2024 was used as part of the anesthetic cocktail for perfusion of a total of nine 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 semi-annual or post approval monitoring inspections. The lab involved in this incident had not yet received stickers in April 2024, at 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, S.E.  
Minneapolis, MN 55455

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

## Ware, Teagan (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, October 24, 2024 11:03 AM  
**To:** (b) (6)  
**Cc:** Nate Koewler; (b) (6); Erin Dickerson; (b) (6); OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] OLAW Non-compliance report for NIH Grant 1R21 NS117978

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11G**. 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](mailto:teagan.ware@nih.gov)

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**From:** (b) (6)  
**Sent:** Thursday, October 24, 2024 8:25 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** [accredit@aaalac.org](mailto:accredit@aaalac.org); Nate Koewler <[koew0004@umn.edu](mailto:koew0004@umn.edu)>; (b) (6); Erin Dickerson <[edickers@umn.edu](mailto:edickers@umn.edu)>; (b) (6)  
**Subject:** [EXTERNAL] OLAW Non-compliance report for NIH Grant 1R21 NS117978

Dear Dr. Wolff,

Attached please find the non-compliance letter referencing the grant above. Please let me know if you have any questions.

Best,

(b) (6)

(b) (6)