



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 9, 2024

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

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 November 27, 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 failure to adhere to IACUC-approved protocols (i.e., recovery of animals without the use of analgesics for procedures approved as non-survival). The final report states that during a post-approval monitoring inspection, a protocol deviation was discovered involving a total of 10 mice that were recovered from anesthesia for a surgery which was approved on the protocol as a non-survival procedure. The final report further states that systemic analgesics were not administered to the animals. However, a local anesthetic was administered prior to the surgery.

Per the final report, the lab confirmed that, going forward, they will ensure that mice remain fully anesthetized with a negative toe pinch response and blink reflex throughout both procedures and the transition between them. The lab has worked with a veterinarian to develop an anesthetic plan that avoids the mouse regaining consciousness at any point. Additionally, future compliance will be monitored by the IACUC via semi-annual inspections and annual post-approval monitoring. With this, the IACUC determined the corrective action plan was adequate, 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.

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: 2024.12.09 12:49:23
-05'00'

cc: IACUC Contact

A3456-11H

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

November 27, 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: 1R01NS118330-01
UMN IACUC #39722A

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. During the inspection, it was discovered that mice undergoing an approved procedure sequence were recovered from anesthesia between the surgical procedure (a craniotomy) and the subsequent imaging procedure, as the mouse was transitioned from gas anesthesia used for surgery to an injectable anesthetic cocktail used for imaging. Because the surgical procedure was approved as a non-survival procedure, systemic analgesics were not administered. After this non-compliance was discovered during post-approval monitoring, the lab indicated that this had occurred for a total of 10 mice between August 10, 2023, and November 14, 2024.

Because the mice had not received a systemic analgesic, they may have experienced pain from the craniotomy during the approximately 20-minute period in which they recovered from anesthesia. A local block with bupivacaine had been administered prior to the surgery.

We want to inform you that we consider this matter closed. The lab has confirmed that, going forward, they will ensure that mice remain fully anesthetized with a negative toe pinch response and blink reflex throughout both procedures and the transition between them. They have worked with a veterinarian to develop an anesthetic plan that avoids the mouse regaining consciousness at any point. Future compliance with this plan will be monitored during semi-annual 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, 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, December 5, 2024 7:48 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 1R01NS118330-01

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11H**. 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 4, 2024 9:11 PM
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 1R01NS118330-01

Dear Dr. Wolff,

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

Best,

(b) (6)

(b) (6)