



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

May 30, 2024

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

Shashank Priya, Ph.D.
Vice President for Research and Innovation
University of Minnesota – Main Campus
(b) (4) Johnston Hall - 101 Pleasant St., SE
Minneapolis, MN 55455

Dear Dr. Priya,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 22, 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 failure to properly monitor animals, improper use of anesthesia, poor aseptic technique, and tissue handling. The final report states on February 20, 2024, six mice experienced complications from an approved surgical procedure. It is stated lab personnel re-dosed the injectable anesthetic cocktail incorrectly and did not properly monitor the mice until the animals had fully recovered from anesthesia. Investigative results determined there were deficiencies in the lab's surgical techniques related to asepsis and tissue handling.

The report states one mouse was found dead, and the remaining animals exhibited signs of pain. After consultation with an RAR veterinarian, two mice required euthanasia and 3 animals were treated with additional analgesics. As a corrective measure, the lab member performing surgery worked with an RAR veterinarian to adjust their incision closure pattern and to modify the anesthetic and analgesic plan. It is understood the surgeon completed formal retraining in aseptic technique, suturing, and rodent anesthesia. Per the report, future compliance will be monitored by semiannual inspections and during annual post-approval monitoring.

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: 2024.05.30 12:47:48
-04'00'

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

cc: IACUC Contact

A3456-11B

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

May 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: R01 CA174777
UMN IACUC # 41211A

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 an issue that was initially noted by veterinary staff and followed up with a self-report from lab staff. The observation and report outlined that on February 20, 2024, 6 mice experienced unexpected complications following an approved minor surgery (castration). It was also noted that lab staff redosed the injectable anesthetic cocktail incorrectly and failed to properly monitor the mice until they had fully recovered from anesthesia. During subsequent investigation of this incident, including observation of surgeries by an RAR veterinarian, deficiencies in the lab's surgical techniques related to asepsis and tissue handling were also identified.

One mouse was found dead. The remaining 5 mice showed signs of pain, and following consultation between lab staff and an RAR veterinarian, two mice required euthanasia, and three were treated with additional analgesics.

We want to inform you that we consider this matter closed. The lab member performing surgery worked closely with an RAR veterinarian to adjust their incision closure pattern and to modify the anesthetic and analgesic plan in the protocol. The surgeon has also completed formal retraining via hands on courses in aseptic technique and suturing and rodent anesthesia. Future compliance, including review of complication rates, will be monitored via semi-annual surgical inspections and annual post approval monitoring.

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: Wednesday, May 29, 2024 10:28 AM
To: (b) (6)
Cc: Erin Dickerson; (b) (6) Nate Koewler; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Non-Compliance Reports

Good morning,

Thank you for providing these 2 reports, which have been assigned as OLAW cases **A3456-11A** (IACUC #38905A) and **A3456-11B** (IACUC #41211A). 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: Wednesday, May 29, 2024 7:30 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Erin Dickerson <edickers@umn.edu>; (b) (6) Nate Koewler <koew0004@umn.edu>; accredit@aaalac.org
Subject: [EXTERNAL] Non-Compliance Reports

On behalf of VPR Shashank Priya, please find the two attached reports of non-compliance.

Best,
(b) (6)