



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

January 10, 2025

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

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 12, 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 adhere to the IACUC-approved protocol. The final report states during a post-approval monitoring inspection, a review of laboratory records revealed an experimental cohort of mice was not monitored as described in the protocol between November 8-21, 2024. It is stated the approved monitoring plan indicated tumor bearing mice would be weighed weekly by lab personnel, and at increased frequency when weight loss reached 10-15%. However, based on the records reviewed, 14 mice had an instance where weight loss was above 10%, but the animals were not weighed again until 3d later. It is stated daily weighing was implemented for all animals in the group at the same time, however some animals should have been designated for daily weighing sooner based on their status.

The report states while the mice with weight loss was greater than 20%, there is a possibility some animals may have met this threshold prior to being identified for euthanasia due to the lack of daily monitoring. It is also stated the animals may have experienced pain/distress during this time. It is understood the principal investigator affirmed that laboratory staff will adhere to the approved monitoring plans moving forward. Email correspondence described the corrective actions taken to prevent future recurrence of a similar incident, which include the following (in summary):

- Retraining lab staff on the requirement for strict adherence to the daily weight-measuring guidelines for animals with 10-15% weight loss.
- Adding color coding to the animal monitoring record form to prompt the lab staff on animal welfare.
- Reducing the number of tumor cells initially injected to produce a less rapidly progressing model.

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

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

Digitally signed by
JACQUELYN T. TUBBS -S
Date: 2025.01.10 09:34:03
-05'00'

cc: IACUC Contact

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 2, 2025 1:21 PM
To: (b) (6) Tubbs, Jai (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD); (b) (6) Nate Koewler; Erin Dickerson
Subject: RE: [EXTERNAL] OLAW non-compliance report for NIH Grant R01 CA 233522

Good afternoon,

Thank you for providing this additional information for OLAW case **A3456-11J**. We will let you know if there are any further questions, otherwise an official response will be sent 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, January 2, 2025 12:49 PM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6) Erin Dickerson <edickers@umn.edu>
Subject: Re: [EXTERNAL] OLAW non-compliance report for NIH Grant R01 CA 233522

Hello Dr. Tubbs,

I apologize for the lack of detail regarding corrective actions in the original report. Corrective actions taken by the lab to prevent recurrence of this reportable incident, and endorsed by the IACUC, are as follows:

- Retraining lab staff on the requirement for strict adherence to the daily weight-measuring guidelines for animals with 10-15% weight loss.
- Adding color coding to the animal monitoring record form to prompt the lab staff on animal welfare. Healthy animals will be marked in green, those requiring daily weight measurements in yellow, and animals to be euthanized in red.
- Reducing the number of tumor cells initially injected to produce a less rapidly progressing model.

Please let me know if you have any questions or need additional information.

Thank you.

(b) (6)

On Mon, Dec 23, 2024 at 8:45 AM Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov> wrote:

Good morning,

I am reviewing the final report, and it does not describe the corrective actions implemented to prevent future recurrence of the reportable incident. Please provide a description the corrective actions developed to address the reportable incident.

Kind Regards,

J. Tubbs

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Monday, December 16, 2024 1:32 PM

To: (b) (6)

Cc: (b) (6)

Nate Koewler <koew0004@umn.edu>; Erin

Dickerson <edickers@umn.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: RE: [EXTERNAL] OLAW non-compliance report for NIH Grant R01 CA 233522

Good afternoon,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11J**. We will send an official response soon.

Best,

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC) Office

(b) (6)

(b) (4) McNamara Ctr
200 Oak St SE (b) (4)
Minneapolis, MN 55455(b) (6)
iacuc@umn.eduwww.research.umn.edu/units/iacuc

December 12, 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 CA 233522
UMN IACUC #39618A

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 review of laboratory records, it was discovered that between November 8, 2024, and November 21, 2024, an experimental cohort of mice were not always monitored by the laboratory according to the schedule approved in the IACUC protocol. The approved monitoring plan indicated that tumor bearing mice would be weighed weekly by laboratory personnel, with the frequency of weighing increasing to daily once weight loss reached 10-15%, to ensure that mice were euthanized promptly when a weight loss of 20% was reached. However, for 14 mice out of the total of 28, records showed an instance where weight loss was over 10% but the animal was not weighed again until three days later. Daily weighing was instituted for the entire group at the same time, but some individual animals should have moved to daily weighing sooner based on their status.

While mice were euthanized as soon as weight loss greater than 20% was detected, there is the potential that some animals may have met this threshold sooner but were not identified for euthanasia due to the lack of daily monitoring and may have experienced pain or distress during this time.

We want to inform you that we believe that appropriate steps have been taken to prevent recurrence and that we consider this matter closed. The principal investigator has confirmed that lab staff will adhere to the monitoring plans approved in the protocol moving forward. Future compliance will be assessed during semi-annual inspections with careful review of monitoring and weight records, as well as 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, 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: Monday, December 16, 2024 1:32 PM
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Good afternoon,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11J**. 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: Monday, December 16, 2024 1:24 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 R01 CA 233522

Dear Dr. Wolff,

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

Best,

(b) (6)