



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

August 23, 2021

Re: Animal Welfare Assurance
#A3294-01 (OLAW Case 2N)

Dr. Jennifer Larsen
Vice Chancellor for Research
Louise and Morton Degen Professor
of Internal Medicine
University of Nebraska Medical Center
987878 University Nebraska Medical Center
Omaha, NE 68198-7878

Dear Dr. Larsen,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 3, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Nebraska Medical Center. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Nebraska Medical Center 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 routine audits a Comparative Medicine Veterinary Technician (VT) identified surgery cards for 5 rats that were incomplete for days 2 and 3 regarding post-operative (post-op) health checks and analgesic administration. Ultimately, it was confirmed that analgesic administration did not occur on post-op days 2 and 3 because the research technician forgot to notify other research staff that they would be unavailable. It is stated there were no reports of animal health issues by CM husbandry or Vet Services during the post-op period. Also, the Protocol Assessment Liaison (PAL) noted that the analgesics were not administered as described per the protocol.

In response to the incident, the following actions were taken by the IACUC:

- The PAL met with the principal investigator (PI), and research staff to provide education for post-op monitoring, providing continuous pain relief, documentation of surgery cards, and following the approved analgesic administration. The PAL requested that the PI provide a backup plan for animal care in case of absence of personnel and assigned the PI and all research staff the AALAS course, Post-procedure Care of Rats and Mice in Research and Minimizing Pain and Distress.
- The PI designated a Laboratory Animal Coordinator (LAC) for the lab and the PAL will assign all training required for a LAC.

It is noted that this project is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Nebraska Medical Center 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: 2021.08.23
15:39:02 -04'00'

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

cc: IACUC Contact



August 3, 2021

Axel V. Wolff, M.S., D.V.M., Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: IACUC Case #2021-03 Final Report

Dear Dr. Wolff:

I am submitting this report in accordance with the requirements of the PHS Policy at IV.F.3. The IACUC has reviewed this incidence of the noncompliance described in this report and categorized it as serious and, therefore, reportable to OLAW.

1. **Animal Welfare Assurance Number:** A3294-01
2. **Grant or Contract Number:** NIH 5R01HL137832-04
3. **Species:** Rats
4. **Effects on Programmatic or Physical Areas:** NA
5. **Explanation of the Situation:**
 - a. While conducting routine audits a Comparative Medicine Veterinary Technician (VT) noted that surgery cards for 5 rats were not complete for days 2 and 3 regarding post-op health checks and analgesic administration. The VT contacted responsible research personnel and they confirmed that post-op checks, and analgesic administration had occurred on the day of surgery and post-op day 1, but not on days 2 and 3 because the research technician forgot to notify other research staff that she would be unavailable. There were no reports of animal health issues by CM husbandry or Vet Services staff during the post-op period.
 - b. It was later noted by the Protocol Assessment Liaison (PAL) that although analgesics were initially administered, they were not administered according to the schedule in the approved protocol.
6. **Actions Taken by the IACUC:**
 - a. The PAL met with the PI, and research staff to provide education for post-op monitoring, providing continuous pain relief, documentation of surgery cards, and following the approved analgesic administration. The PAL requested that the PI provide a backup plan for animal care in case of absence of personnel and assigned the PI and all research staff the AALAS course, Post-procedure Care of Rats and Mice in Research and Minimizing Pain and Distress.
 - b. The PI designated a Laboratory Animal Coordinator (LAC) for the lab and the PAL will assign all required training required for a LAC.

c. The PI must submit a written plan accessible to all lab members that ensures that all animal care responsibilities for all animal procedures including surgery and post-op monitoring are always covered. The plan must include contingency coverage in case of personnel absence and a signed assurance from the PI acknowledging full responsibility for ensuring enactment of the plan.

7. Implementation Schedule:

a. Completed.

If you have any questions or require any further information, please do not hesitate to contact me.

Respectfully,

(b) (6)

Jennifer Larsen, MD
Institutional Official
University of Nebraska Medical Center
Vice Chancellor for Research

(b) (6)

PH (b) (6)

FAX (b) (6)

Email: jlarsen@unmc.edu

cc: Robert G. Bennett, Ph.D., IACUC Executive Chair

(b) (6)

John F. Bradfield, D.V.M., Ph.D. Attending Veterinarian/Director Comparative Medicine

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 13, 2021 7:26 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UNMC IACUC Case #2021-03 Final Report

Thank you for this report. We will send a response soon.
Axel Wolff

From: (b) (6)
Sent: Thursday, August 12, 2021 2:36 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Bennett, Robert G <rgbennet@unmc.edu>; (b) (6) Larsen, Jennifer L <jlarsen@unmc.edu>; Bradfield, John F <john.bradfield@unmc.edu>; IACUCORA, UNMC <IACUCORA@unmc.edu>
Subject: UNMC IACUC Case #2021-03 Final Report

Dear Dr. Wolff,
Please see the attached report for IACUC Case #2021-03. Please let us know if you have any questions.

Sincerely,
(b) (6)

(b) (6)

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