



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

June 22, 2020

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

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 June 17, 2020 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 follow the IACUC-approved protocol and the surgery policy. The final report states that a research technician was not compliant with the surgery policy that requires 3-day post-operative monitoring of animals. The technician did not check the rats and failed to administer analgesics on post-op day one as required by the protocol. The report states the rats did receive analgesics at time of surgery and post-op days 2 and 3. The principal investigator (PI) stated the technician is usually reliable and was not known for failure to perform assigned responsibilities. Room access records for previous surgeries (6 months prior) were reviewed and confirmed research staff had accessed the animal room for 3d following surgery in all instances.

The IACUC subcommittee reviewed the incident on May 21, 2020 and determined the incident was reportable. The committee approved the following corrective action plan:

- The research technician will not have animal contact for 30d followed by supervised animal activity for 3mo and retraining.
- The technician and PI will meet with IACUC Chair to ensure a full understanding of the requirements and expectations of the IACUC prior to conducting independent animal work.
- All personnel assigned to perform or assist in surgery must complete the CM Aseptic Rodent Survival Surgery course.
- One person listed on the active protocols must be identified as a Laboratory Animal Coordinator (LAC). The LAC will complete additional training modules as assigned and serve as liaison to IACUC and CM as point of contact.

It is noted that this research is supported by PHS funds. 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: 2020.06.22 12:43:02
-04'00'

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

cc: IACUC Contact



June 17, 2020

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 #2020-04 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 incident described in this report and determined it was reportable to OLAW.

1. **Animal Welfare Assurance Number:** A329401
2. **Grant or Contract Number:** NIH 5P01HL126796-05 AND NIH 2R01HL126796-05
3. **Species:** Rats
4. **Effects on Programmatic or Physical Areas:** N/A
5. **Explanation of the Situation:**
 - a. A research technician did not follow the surgery policy which requires monitoring animals for 3 days following surgery. The technician did not check the rats or administer analgesics on post-op day one as required by the protocol. The rats received analgesics at the time of surgery and on day two and day three post-op.
 - b. The PI stated that the technician has previously been very reliable and to his knowledge has never failed to perform her assigned responsibilities. He also indicated that he is aware that she is dealing with some personal issues at this time that he feels may be affecting her work performance. Room access records for previous surgeries dating back six months were checked and confirmed research staff had accessed the animal room for three days following surgery in all instances.
6. **Actions Taken by the IACUC:**
 - a. The IACUC Subcommittee reviewed this incident on May 21, 2020 and determined this to be a reportable incident that affected animal welfare. The IACUC also required the following preventative corrective action:
 1. The research technician will have no direct contact with animals for 30 days followed by supervised animal activity for 3 months and re-training. Prior to continuing independent animal work in the facility the technician and the PI will meet with an IACUC Chair to ensure the research technician has a full understanding of the requirements and expectations of the IACUC.
 2. All personnel assigned to perform or assist in surgery must complete the CM Aseptic Rodent Survival Surgery course as soon as possible.
 3. One person listed on the active protocols must be identified as a Laboratory Animal Coordinator (LAC). The LAC will complete additional training modules as assigned, and will serve as the liaison to

the IACUC and CM and as the main point of contact. The Protocol Assessment Liaison will coordinate necessary training and communications with the designated LAC.

7. Implementation Schedule:

A. In Process

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, June 19, 2020 7:08 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UNMC IACUC Case #2020-04 Final Report

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Thursday, June 18, 2020 5:14 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>
Subject: UNMC IACUC Case #2020-04 Final Report

Dear Dr. Wolff,
Please see the attached report for IACUC Case #2020-04. Please let us know if you have any questions.

Sincerely,
(b) (6)

(b) (6)

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