



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

March 24, 2020

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

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 March 10, 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 (IACUC Case #2019-06). According to the information provided, OLAW understands that two incidents occurred wherein a lab failed to use aseptic technique and preform post-operative monitoring of mice. Upon review of the incidents by the IACUC, the PI voluntarily stopped all procedures. The related animal activity was PHS funded.

Corrective actions included the IACUC requiring all assigned research personnel involved in rodent survival surgery to complete the Aseptic Rodent Surgery course and have their proficiency evaluated by veterinary staff. Continuous assessment would be conducted by the veterinary staff and the Protocol Assessment Liaison who would report back to the IACUC. The IACUC also required the PI to appoint a Laboratory Animal Coordinator (LAC) who, after proper training, would be responsible for oversight and monitoring all animal protocol activities and training for the lab. The LAC would also serve as liaison between the lab, Comparative Medicine and the IACUC, sharing opportunities for education and ensuring compliance in all research activities.

The prompt consideration of this matter by the University of Nebraska Medical Center was consistent with the philosophy of institutional self-regulation. Similarly, the completed and in-process actions taken to resolve the issues and prevent recurrence were appropriate. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

March 10, 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 #2019-06 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 determined it was reportable to OLAW.

1. **Animal Welfare Assurance Number:** A3294-01
2. **Grant or Contract Number:** NIH 5R01CA216853-03
3. **Species:** Mice
4. **Effects on Programmatic or Physical Areas:** N/A
5. **Explanation of the Situation:**
 - a. There were two instances in which research personnel used improper aseptic surgical technique, and did not follow their approved protocol for post-operative monitoring of mice. The mice were in good health after the first occurrence, but on the second occurrence, veterinary intervention was required.
 - b. The Post Approval Liaison (PAL) was promptly notified and met with the Principal Investigator and the research personnel that performed the procedure and post procedural care to discuss the incident and the discrepancies from the approved protocol. A repeat incident occurred following the initial meeting with the PI and research personnel but prior to re-training. An IACUC subcommittee meeting was held the same day as but after the second incident.
6. **Actions Taken by the IACUC:**
 - a. The IACUC Subcommittee reviewed the incidents on December 20, 2019 and on January 16, 2020. The full IACUC reviewed the incident on February 19, 2020. The investigator agreed to discontinue all procedures until research personnel were retrained and their competency confirmed. The IACUC will continue to monitor laboratory activities by conducting regular audits after the personnel are approved to resume activities. The committee required that all research personnel assigned to perform, or

assist in rodent survival surgery must complete the UNMC "Aseptic Rodent Surgery Training" course. Veterinary staff will assess the proficiency of each person before they are allowed to perform procedures independently. The committee also implemented continuous monitoring by CM veterinary staff and the Protocol Assessment Liaison (PAL), who will provide the IACUC with progress reports at FC meetings

- b. The committee also required that the PI designate one person to serve as the Laboratory Animal Coordinator (LAC) once they are certified to perform survival surgery. The responsibilities of the LAC are as follows: 1) to complete a series of LAC training modules as determined by the IACUC, 2) be responsible for daily oversight and monitoring of all approved animal protocol activities and provide training as needed to laboratory personnel, and 3) serve as the liaison between the lab and CM and the IACUC, sharing opportunities for education and ensuring compliance in all research activities.

7. Implementation Schedule:

A. In Progress

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: Tuesday, March 17, 2020 10:37 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UNMC IACUC Case #2019-06 Final Report

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

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, March 17, 2020 9:36 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: UNMC IACUC Case #2019-06 Final Report

Dear Dr. Wolff,
Please see the attached report for IACUC Case #2019-06. Please let us know if you have any questions.

Sincerely,
(b) (6)

(b) (6)

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