



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

November 21, 2022

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

Dr. Ken Bayles  
Vice Chancellor for Research  
University of Nebraska Medical Center  
987878 Nebraska Medical Center  
Omaha, NE 68198

Dear Dr. Bayles,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 20, 2022 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Nebraska Medical Center. According to the information provided, OLAW understands that three mice were not euthanized in accordance with the institutional policy for Premature Euthanasia and Humane Endpoints. The Comparative Medicine (CM) staff placed a Health Alert card on the cage with instructions to euthanize the animals and notified the laboratory. Research staff confirmed that they received the alert and understood the veterinary instruction to euthanize the animals but decided to delay euthanasia after assessing the mice. The following day, one of the mice was found dead by CM staff. The CM veterinarian contacted the research staff and instructed them to immediately euthanize the remaining 2 mice. The research staff complied. The mice involved in this incident were supported by PHS funds.

Corrective and preventive measures included: 1) Counseling and retraining of the principal investigator (PI) and study personnel regarding the importance of humane endpoints, post-procedure monitoring, and recognizing pain and distress. Education was also provided regarding veterinary oversight and the institutional veterinary alert card system. 2) The laboratory must notify the post-approval monitoring liaison (PAL) prior to the start of each experiment. Monitoring must be documented according to the approved protocol on observation forms provided by the PAL. 3) Veterinary services or the PAL will randomly monitor the animals and check room logs for the duration of each experiment for the next 3 months. 4) A bulletin on premature euthanasia, humane endpoints, veterinary notifications, and laboratory management and monitoring responsibilities was created and disseminated by the PAL. 5) The PAL office will schedule a seminar open to all animal research personnel that will cover the topics in the bulletin. All research personnel involved in this incident will be required to attend.

OLAW appreciates the consideration of this matter by the University of Nebraska Medical Center which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M. Engel -S  
Date: 2022.11.21 14:29:58 -05'00'

Robyn M. Engel, DVM  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare

*Page 2 - Dr. Bayles*  
*November 18, 2022*  
*OLAW Case A3294-2P*

**cc: IACUC contact**



Date October 20, 2022

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 #2022-06 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 incidence of 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 5R01CA218545-05, 5R01CA241752-02
3. **Species:** Mice
4. **Effects on Programmatic or Physical Areas:** NA
5. **Explanation of the Situation:**
  - a. Comparative Medicine (CM) Staff found a cage of three mice that required euthanasia according to the IACUC Policy for Premature Euthanasia and Humane Endpoints. CM Staff placed a Health Alert card on the cage with instructions to euthanize all three mice and notified the PI and research personnel. Research staff confirmed that they received communication from CM and understood the veterinary instruction to euthanize the mice, but after assessing the mice, decided to delay euthanasia for one more day.
  - b. The following day, CM Staff found that the mice had not been euthanized and one mouse was deceased. The research staff had added notes to the Health Alert Card indicating that the mice would be monitored without consulting with the CM Veterinarian. The CM Veterinarian immediately contacted the research staff and instructed them to immediately euthanize the remaining two mice. CM staff confirmed that the mice had been euthanized.
6. **Actions Taken by the IACUC:**
  - a. Immediate corrective action included a meeting with the Principal Investigator (PI), study personnel, and the Post Approval Liaison (PAL) staff to discuss the incident and provide education on humane endpoints and post-procedure monitoring.
  - b. The AV, CM Clinical Veterinarians and PAL staff met with all research staff to provide education on humane endpoints, veterinary alert cards and veterinary care and oversight.
  - c. The IACUC subcommittee reviewed the incident on September 20 and 29, 2022, and agreed to recommended actions as described below. All IACUC members were invited to attend the meetings.

- i. The Institutional Official (IO) and/or the IACUC Chairs will schedule a meeting with the Department Chair to discuss the impact of the incident.
- ii. All research staff must complete Humane Endpoints and Post Procedure Monitoring of Rodents, Recognizing Pain, and Distress on AALAS Learning Library courses no later than October 20<sup>th</sup>, 2022.
- iii. The PI and/or the Laboratory Animal Coordinator will be required to notify the PAL office prior to the start of each experiment with a schedule of approved procedures to be performed. The PI and staff will be required to document animal monitoring according to the approved protocol on observation forms provided by PAL.
- iv. Veterinary Services or PAL will randomly monitor the animals and check room monitoring logs and room access records for the duration of each experiment. After 3 months PAL staff in conjunction the IACUC chairs and the Attending Veterinarian (AV) will determine if additional monitoring is necessary.
- v. The PAL office will create and publish a bulletin on Premature Euthanasia and Humane Endpoints, CM veterinary notifications, and the laboratory monitoring & management responsibilities. This was completed and emailed on 10/10/2022.
- vi. The PAL office will schedule a seminar open to all UNMC animal research personnel that will provide education presented by IACUC and veterinary staff on Premature Euthanasia & Humane Endpoints, CM veterinary notifications, and laboratory monitoring & management responsibilities. All research personnel from the lab involved in this incident that will be required to attend.

7. September 30, 2022, the Institutional Official accepted the full recommendation of the subcommittee.

**8. Implementation Schedule:**

- a. All corrective/preventative actions assigned to date have been completed or are in process.

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

Respectfully,

(b) (6)

Kenneth W. Bayles, PhD  
Institutional Official  
University of Nebraska Medical Center  
Vice Chancellor for Research  
PH (b) (6)  
Email: [kbayles@unmc.edu](mailto:kbayles@unmc.edu)

(b) (6)

cc:

(b) (6)

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

**McCoy, Devora (NIH/OD) [E]**

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**From:** (b) (6) on behalf of IACUCORA, UNMC  
<IACUCORA@unmc.edu>  
**Sent:** Thursday, October 20, 2022 1:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Bayles, Ken W; Bradfield, John; (b) (6) IACUCORA, UNMC;  
(b) (6)  
**Subject:** [EXTERNAL] UNMC IACUC Case #2022-06 Final Report  
**Attachments:** OLAW IACUC 2022-06 final report .pdf  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear Dr. Wolff,  
Please see the attached report for IACUC Case #2022-06. Please let us know if you have any questions.

Sincerely,

(b) (6)

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, October 20, 2022 3:01 PM  
**To:** IACUCORA, UNMC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: UNMC IACUC Case #2022-06 Final Report

Good afternoon (b) (6)

Thank you for sending us this report and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
301-435-2390

**From:** (b) (6) On Behalf Of IACUCORA, UNMC  
**Sent:** Thursday, October 20, 2022 1:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Bayles, Ken W <kbayles@unmc.edu>; Bradfield, John <john.bradfield@unmc.edu>; (b) (6)  
(b) (6) IACUCORA, UNMC <IACUCORA@unmc.edu>;  
(b) (6)  
**Subject:** [EXTERNAL] UNMC IACUC Case #2022-06 Final Report

Dear Dr. Wolff,  
Please see the attached report for IACUC Case #2022-06. Please let us know if you have any questions.

Sincerely,

(b) (6)

