



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
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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

May 4, 2022

Re: Animal Welfare Assurance
#A3294-01 (OLAW Case 20)

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 April 18, 2022 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 (UNMC). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the UNMC Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to institutional policies/procedures and failure to perform euthanasia according to approved procedures. The final report states the IACUC received an anonymous report that a technician was not managing a breeding colony of mice appropriately. There was also a concern that euthanasia may not have been performed as per UNMC-approved procedure. Investigative results from the IACUC determined the colony was not managed adequately and the technician did not perform euthanasia according to approved procedures.

In response to these findings, a meeting was held with the Principal Investigator (PI), the research technician, IACUC Chair, co-chair, Attending Veterinarian (AV), and the Post Approval Liaison (PAL). The AV and PAL held a meeting with all technicians in the laboratory to discuss euthanasia and protocol requirements. PAL assigned all personnel additional euthanasia and breeding management training. A Laboratory Animal Coordinator (LAC) was established for the lab and PAL assigned required training for the LAC. It is understood a subcommittee reviewed the matter and recommended the following actions:

- The PI is required to provide the IACUC an expected plan of experimental needs for the next 6 months including personnel responsibilities and the approximate number of animals/strains that will need to be produced from the breeding colonies.
- The PI is required to assign additional personnel to assist in managing the breeding colony in case of unexpected absences or increased experimental needs.
- Protocol personnel are required to meet with Comparative Medicine's (CM) Research Technical Services (RTS) staff to review the current breeding colony management plan and discuss options to eliminate excessive breeding.

- CM RTS is required to conduct weekly breeding colony checks with research staff to inspect breeding cages of the strains listed in the 6-month plan and report to the PAL. RTS will provide guidance to research personnel based on observations.
- The PI is required to visit the animal facility every 1-2 weeks with his staff to go over breeding production and management progress. The PI must submit a progress report to PAL after 3 months. PAL will evaluate the 3-month report and the RTS reports to determine if continued monitoring is necessary.

Per the report, the Institutional Official accepted the full recommendation of the subcommittee and many of the corrective actions have been completed. It is noted that this research 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: 2022.05.04
11:19:55 -04'00'

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

cc: IACUC Contact



April 18, 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 #2022-03 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 5R01EY010542-26 and Yale Subcontract GR111940 (CON-800)
3. **Species:** Mice
4. **Effects on Programmatic or Physical Areas:** NA
5. **Explanation of the Situation:**
 - a. An anonymous report was received that indicated a technician was not managing the breeding colony appropriately which resulted in unplanned matings and offspring, and experimental animals becoming pregnant. Additionally, there was concern that euthanasia may not have been performed according to UNMC-approved procedure.
 - b. Following investigation by the IACUC it was determined that the colony was not managed adequately, and that the technician did not perform euthanasia according to approved procedures.
6. **Actions Taken by the IACUC:**
 - a. Immediate corrective action included a meeting with the Principal Investigator (PI), the research technician, IACUC Chair, co-chair, Attending Veterinarian (AV), and the Post Approval Liaison (PAL).
 - b. The AV and PAL met with all technicians in the lab to discuss euthanasia and protocol requirements. PAL assigned all personnel additional euthanasia and breeding management training. A Laboratory Animal Coordinator (LAC) was identified for the laboratory and PAL assigned required training for the LAC.
 - c. The IACUC subcommittee reviewed the incident on March 15 and April 11, 2022, and recommended additional actions as described below. All IACUC members were invited to attend the meetings.

- 1) The PI is required to provide the IACUC an expected plan of experimental needs for the next 6 months including personnel responsibilities and the approximate number of animals/strains that will need to be produced from the breeding colonies.
- 2) The PI is required to assign additional personnel to assist in managing the breeding colony in case of unexpected absences or increased experimental needs.
- 3) Protocol personnel are required to meet with Comparative Medicine's (CM) Research Technical Services (RTS) staff to review the current breeding colony management plan and discuss options to eliminate excessive breeding.
- 4) Comparative Medicine (CM) Research Technical Services (RTS) is required to conduct weekly breeding colony checks with research staff to inspect breeding cages of the strains listed in the 6-month plan and report to the Protocol Assessment Liaison (PAL). RTS will provide guidance to research personnel based on observations.
- 5) The PI is required to visit the animal facility every 1-2 weeks with his staff to go over breeding production and management progress. The PI must submit a progress report to PAL after 3 months. PAL will evaluate the 3-month report and the RTS reports to determine if continued monitoring is necessary.

7. April 19, 2022, the Institutional Official accepted the full recommendation of the subcommittee.

8. Implementation Schedule:

- a. All corrective/preventative action assigned to date has been completed except 4) and 5) above, which are 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
Administrative Assistant: Pamela Welch (pswelch@unmc.edu)

(b) (6)

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: Monday, April 25, 2022 7:30 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UNMC IACUC Case #2022-03 Final Report

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

From: (b) (6)
Sent: Friday, April 22, 2022 11:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Larsen, Jennifer L <jlarsen@unmc.edu>; Bradfield, John F <john.bradfield@unmc.edu>; Bennett, Robert G <rgbennet@unmc.edu>; (b) (6) IACUCORA, UNMC <IACUCORA@unmc.edu>
Subject: [EXTERNAL] UNMC IACUC Case #2022-03 Final Report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,
Please see the attached report for IACUC Case #2022-03. Please let us know if you have any questions.

Sincerely,

(b) (6)

The information in this e-mail may be privileged and confidential, intended only for the use of the addressee(s) above. Any unauthorized use or disclosure of this information is prohibited. If you have received this e-mail by mistake, please delete it and immediately contact the sender.