

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

April 11, 2017

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

Re: Animal Welfare Assurance #A3294-01 (OLAW Case 2D) IACUC Case # 2017 - 02

Ernest D. Prentice, Ph.D.
Associate Vice Chancellor for
Academic Affairs & Regulatory Compliance
University of Nebraska Medical Center
987878 University Nebraska Medical Center
Omaha, NE 68198-7878

Dear Dr. Prentice,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 6, 2017 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Nebraska Medical Center. According to the information provided, OLAW understands that six mouse pups died due to lack of milk because the mother had died and the litter was left with only the father. The husbandry technician misidentified the sex of the dead mother and failed to promptly notify the laboratory staff of the death. Two pups had survived and were transferred to a nursing mother but subsequently also died.

The corrective actions consisted of counseling the technician on identifying the sex of mice and on the procedures for reporting dead animals. The laboratory and animal care staff were trained on sexing mice, the technician was additionally counseled, a new procedure was implemented addressing notification of research staff when a dead adult rodent is found with a litter, and all research staff was informed to keep contact information current to allow notification about animal issues.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Signature

Axel Wolff, M.S., D.V.M. Director Division of Compliance Oversight

cc: IACUC Chair



NEBRASKA'S HEALTH SCIENCE CENTER

April 6, 2017

ASSOCIATE VICE CHANCELLOR FOR ACADEMIC AFFAIRS

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 #2017-02

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 and adverse event 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: NA
- 3. Species: Mice
- 4. Effects on Programmatic or Physical Areas: No
- 5. Explanation of the Situation:
 - a. A Comparative Medicine (CM) husbandry technician removed a dead adult mouse from a cage with a pair of adults and a litter of 8 pups. The husbandry technician failed to correctly identify the sex of the dead mouse, which was the lactating mother. 8 pups were left with the male mouse. The husbandry technician did not notify the laboratory the same day the female was removed which is a CM standard procedure. The lab was notified the next day.
 - b. Research staff checked on the pups immediately, but did not confirm that the dead animal removed was the male because the pups appeared comfortable and they did not want to handle them unnecessarily. The next morning the research technician found that 6 of the 8 pups had died. It was confirmed that the pups died because they did not have access to milk. The research technician consulted with the CM veterinarian and the two surviving pups were at that point transferred to another animal cage that had a nursing mother. The two pups did not survive.
 - c. The research technician notified the CM clinical veterinarian and the Protocol Assessment Liaison (PAL) with an email expressing the lab's concerns about the incident and the unfortunate outcome that resulted in the death of 8 pups. PAL responded immediately and assured the technician and the PI that a complete investigation of the incident would be initiated immediately.
 - d. The Attending Veterinarian (AV), the Institutional Official (IO), and the IACUC Executive Chairman were informed of the incident and the concern expressed by the laboratory personnel.
 - e. The Manager of Operations and PAL met with the husbandry technician to review the incident and gather information. They examined the remaining mouse to confirm the sex of the mouse and reviewed anatomical differences and proper procedure to be followed when a dead animal is found.
 - f. PAL met with the AV and the Assistant Director of Operations for CM and discussed the incident and the labs concerns, and a meeting was scheduled with the IO and the PI.

- g. A meeting was held with the IO, AV, and Assistant Director of Operations, PAL, and the PI. The PI assured the everyone that the concerns expressed from his group were initiated from a position of caring about animal welfare. His lab also felt that the IACUC and Comparative Medicine share this position of caring about ethical animal care. Measures to prevent future incidents and facilitate a more collegial relationship between the PI's lab and CM husbandry staff were discussed. PAL included that a meeting would be scheduled with him and his laboratory to review all of the information gathered and discuss preventative/corrective action to be implemented. The PI was also assured by PAL that the investigation would follow policy and that he would be kept informed of all steps of the investigation, all information acquired, and the formal review process.
- h. CM and the IACUC Subcommittee implemented the following preventative/corrective action plan:
 - 1. Staff training, using a power point presentation, on sexing mice was done at the next scheduled staff meeting. Complete
 - 2. Hands on training on sexing mice were completed with all husbandry staff that work directly with the animals. Complete
 - 3. Individual counseling with the husbandry technician was completed by the Assistant Director of Operations and the husbandry technician's personnel file was documented. Complete
 - 4. A new procedure was implemented for informing research staff about dead animals found with litters present. The CM procedure for notifying Pls/research staff that a dead adult rodent with a litter present was found will be handled as a "Critical" situation, which means it will be marked with a Veterinary Alert card and addressed by veterinary staff immediately to ensure the PI is notified and pups are attended to. If Veterinary Services is unable to reach the PI/research staff they have the authority to use appropriate treatment measures including euthanasia of pups if necessary. Complete
 - 5. PAL education was sent to all research personnel addressing procedures for CM staff to be able to notify them about animal needs and the importance for contact information to be up to date to ensure someone from the lab is reachable at all times. **Complete**

6. Actions Taken by the IACUC:

- a. Following review of this incident by the IACUC subcommittee (IS) the recommendation was that this incident did constitute reportable noncompliance, and animal welfare was jeopardized. The subcommittee also recommended modifications to the corrective/preventative action plan.
- b. On April 5, 2017 the full IACUC voted to accept all recommendations of the IS as written.

7. Implementation Schedule:

a. All corrective/preventative action has been implemented and completed as indicated above.

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

Sincerely,

Signature

Ernest D. Prentice, Ph.D.
Institutional Official
Associate Vice Chancellor for Academic Affairs
Regulatory Compliance

cc: Robert G. Bennett, Ph.D., IACUC Executive Chair Robert S. Dixon, D.V.M., Director Comparative Medicine

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, April 06, 2017 12:09 PM

To:

Secondary Individual

Subject:

RE: Initial Report of Noncompliance UNMC/UNO IACUC Case #2017-02

Thank you for this report, econdary Individua We will respond soon.

Axel Wolff

From: Secondary Individual mailtondary Indivi@unmc.edu]

Sent: Thursday, April 06, 2017 11:46 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Prentice, Ernest <edprenti@unmc.edu>; IACUCORA, UNMC <IACUCORA@unmc.edu>; Dixon, Robert S

<rsdixon@unmc.edu>; Bennett, Robert G <rgbennet@unmc.edu>; Secondary Individual @unmc.edu>

Subject: Initial Report of Noncompliance UNMC/UNO IACUC Case #2017-02

April 6, 2017

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 #2017-02

Secondary Individual

Protocol Assessment Liaison (PAL) Regulatory Affairs, IACUC

Phone: Phone Number

Cell: Phone Number

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