



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>

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

July 12, 2017

Re: Animal Welfare Assurance
A3459-01 [OLAW Case R]

Dr. Debora Hamernik
Interim Associate Vice Chancellor for Research
University of Nebraska - Lincoln
(b) (4) Mussehl Hall, PO Box 830720
Lincoln, NE 68583-0720

Dear Dr. Hamernik,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 30, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Nebraska. According to the information provided, OLAW understands that the current situation involved a Principal Investigator (PI) who had been involved in previous noncompliance which had been reported to this Office. The specific problem consisted of housing mice outside of the animal facility for extended time periods under noncompliant conditions. The mice were not exposed to an appropriate light cycle, cages were not cleaned regularly, and there was inadequate ventilation.

The corrective actions consisted of removing the mice from the laboratory and transferring them to the Attending Veterinarian's holding protocol and stopping all animal activities. The Institutional Animal Care and Use Committee (IACUC) terminated the PI's protocols and suspended the animal use privileges for three years. Prior to starting animal activities the PI must undertake retraining, complete the Assistant Laboratory Animal Technician exam, work with a senior co-PI, and will have protocols approved for only one year.

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 IACUC to comply with the PHS Policy. Please also inform the funding component about the termination of the projects. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Kelly Heath, D.V.M., Attending Veterinarian

June 30, 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 Project Number and Title - **Project #1484: Mechanisms of non-coding RNAs and energy metabolic signaling in the pathogenesis of nutritional associated metabolic diseases and Project #1489: Total and Conditional Knockout Mouse Breeding**

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:** A3459-01
2. **Grant or Contract Number:** 1 P20 GM104320-01A1, 5 P20 GM104320-02, 5 P20 GM104320-03
3. **Species:** Mouse
4. **Effects on Programmatic or Physical Areas:** None
5. **Explanation of the Situation:** **Update of Case A3459-01 [OLAW Case R]** reported on 10 May 2017

History and background information: On 10 May 2017 we reported a noncompliance issue with the PHS Policy on Humane Care and Use of Laboratory animals at the University of Nebraska – Lincoln. Your office responded with a letter dated 15 May 2017 stating that appropriate actions had been taken to investigate, correct, and prevent recurrence of the noncompliance.

On 14 June 2017 a whistle blower informed the IACP office that the PI was continuing to work in a non-compliant manner that included housing animals for extended periods of time outside the animal facility in an unapproved manner. The PI had requested animals to be transported to the laboratory for a terminal procedure on 7 June 2017 that was to be completed in 12 hours or less. Upon notification on 14 June 17 two IACUC members completed a post approval monitoring visit and discovered animals that had been housed in a noncompliant manner for a minimum of a week inside individually ventilated cages, that were enclosed in a rubber tote without access to proper light cycle, sanitation or mechanical ventilation, which is a clear violation of animal care and use regulations. The animals were removed from the laboratory, a work stop order was issued for all work by this PI and all animals were transferred to the Attending Veterinarian's holding protocol for appropriate care.

6. Actions Taken by the IACUC:

On Tuesday, 28 June 2017 the IACUC discussed the work stop and invited the PI to come answer questions. The PI declined to attend this meeting. The off-protocol work was reported to the IACUC Institutional Official (Dr. Debora L. Hamernik, UNL Interim Associate Vice Chancellor for Research). As required, the off-protocol work was also reported by telephone to the National Institutes of Health, Office of Laboratory Animal Welfare on 30 June 2017. By majority vote, both IACUC Protocols 1484 and 1489 were suspended and will be terminated. Additional action taken by the committee and approved by majority vote include the following:

- The PI of record in this case will not be allowed to use vertebrate animals for a period of 3 years at the University of Nebraska-Lincoln

The IACUC also voted and approved the following mitigation steps that the PI must complete before using vertebrate animals for research:

- PI must complete IACUC 101 and report back to the IACUC;
- PI must complete the Assistant Laboratory Animal Technician (ALAT) exam through AALAS;
- PI must have a senior level co-PI with previous animal experience on future protocols; and
- Any new protocols written by the PI after the 3-year suspension is complete will be given a 1-year approval.

- 7. Outcome:** The PI is currently not eligible to use vertebrate animals for research at the University of Nebraska-Lincoln for 3 years. The PI must complete all mitigations to the satisfaction of the IACUC by June 28, 2020 to be considered for reinstatement of privileges to use vertebrate for research, which will not occur before June 28, 2020.

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

Sincerely,

(b) (6)

Debora L. Hamernik, PhD
Interim Associate Vice Chancellor for Research
Associate Dean, Agricultural Research Division
Associate Director, Nebraska Agricultural Experiment Station

c: Interim Vice Chancellor for Research and Economic Development
IACUC Chair
Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 03, 2017 1:13 PM
To: Kelly Heath; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Wolff, Axel (NIH/OD) [E]
Subject: RE: Final Report of Non-Compliance A3459-01

Thank you for this update Dr. Heath. Doctor Wolff will review your further corrective measures and send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Kelly Heath [mailto:kheath3@unl.edu]
Sent: Monday, July 03, 2017 12:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Subject: Final Report of Non-Compliance A3459-01
Importance: High

Dear Dr. Wolff

Please find attached our follow up final report of Non-Compliance for case number A3459-01 [OLAW Case R]. Please let me know if you have any additional questions. Thank you for your assistance during our telephone conversation on June 30th.

Kind Regards,

Kelly

**Kelly D Heath**

Director and Attending Veterinarian

Institutional Animal Care Prog

1915 N. 38th Street

(b) (4) UNL, 88583-0720

University of Nebraska-Lincoln

Cell (b) (6)

Office (b) (6)



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May 15, 2017

Rc: Animal Welfare Assurance
A3459-01 [OLAW Case R]

Dr. Debora Hamernik
Interim Associate Vice Chancellor for Research
University of Nebraska - Lincoln
(b) (4) Mussehl Hall, PO Box 830720
Lincoln, NE 68583-0720

Dear Dr. Hamernik,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 10, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Nebraska- Lincoln, following up on an initial telephone report on April 26, 2017. According to the information provided, OLAW understands that a five month old mouse was toe clipped for identification. Analgesia was not provided and the bleeding at the site could not be stopped. The approved protocol did not include toe clipping for any reason and did not include mouse breeding which was also being conducted. There was a discrepancy between the transgenic mouse strains listed on the Institutional Biosafety Committee (IBC) protocols and the Institutional Animal Care and Use Committee (IACUC) protocols.

The immediate action taken upon discovery consisted of anesthetizing the mouse and applying tissue glue and having the veterinarian administer analgesia. The Attending Veterinarian directed the Principal Investigator (PI) to stop the animal activities and transfer the mice to the holding protocol. The IACUC counseled the PI on not using toe clipping for identification of older mice and directed the PI and staff to undergo retraining on protocols and animal handling. The PI must verify all strains of mice with the IBC and submit new protocols for the research and breeding. The protocols were subsequently approved by the IACUC and all corrective actions were completed, thus allowing the PI to resume animal activities.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

May 10, 2017

Axel V. Wolff, M.S., D.V.M., Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge I, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: IACUC Project Number and Title Project #1292: Mechanisms of non-coding RNAs and energy metabolic signaling in the pathogenesis of nutritional associated metabolic diseases.

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:** A3459-01
2. **Grant or Contract Number:** 1 P20 GM104320-01A1, 5 P20 GM104320-02, 5 P20 GM104320-03
3. **Species:** Mouse
4. **Effects on Programmatic or Physical Areas:** None
5. **Explanation of the Situation:**

History and background information: On Tuesday, March 28, 2017 an animal care technician was asked to help with a 5 month old mouse that had been toe clipped. Graduate students were told by the Principal Investigator (PI) to clip the toe for identification purposes. After clipping the toe, they were unable to stop the bleeding. The technician immediately got the facility supervisor to help anesthetize the mouse and glue the tissue shut. The clinical veterinarian was called and he administered appropriate pain medications to the mouse. Animal Care Staff notified the Institutional Animal Care Program (IACP) office about the incident. The Attending Veterinarian immediately contacted the PI for a meeting. After the meeting, a work stop was issued and all animals were transferred from protocol 1292 to the Attending Veterinarian's holding protocol.

The PI's protocol was evaluated to determine if it included toe-clipping as an approved method to identify individual mice. Analysis of the PI's protocol revealed that the PI did not have approval to toe clip mice of this age for any purpose. It was also noted that the PI was breeding mice without an approved protocol. There was also a lack of concordance regarding transgenic strains of mice listed on the Institutional Biosafety Committee (IBC) protocols and IACUC protocols.

6. Actions Taken by the IACUC:

On Tuesday, April 18, 2017 the IACUC discussed the work stop and invited the PI to a meeting with the IACUC to answer additional questions. The IACUC Chair reminded the PI that toe clipping was not an appropriate method of identification for 5 month old mice and that subsequent actions must be taken before the work stop would be lifted. The off protocol work was reported to the IACUC Institutional Official (Dr. Debora L Hamernik, UNL Interim Associate Vice Chancellor for Research), and as required, the National Institutes of Health, Office of Laboratory Animal Welfare by telephone. The IACUC decided to keep the work stop in place until the PI completes the following items:

- PI and staff in her laboratory must complete a protocol training session with the IACP Assistant Director.
- PI and staff in her laboratory must complete an animal handling training session with the Clinical Veterinarian.
- PI must verify all strains of mice with the IBC.
- PI must submit a new research protocol for the use of animals.
- PI must submit a new breeding protocol.

7. Outcome:

- The PI and staff in her laboratory completed the training given by the IACP Assistant Director on April 28, 2017.
- The PI and staff in her laboratory completed the animal handling training conducted by the Clinical Veterinarian on May 8, 2017.
- The PI met with a biosafety officer to confirm all transgenic strains of mice that should be listed on her IBC protocol on April 27, 2017.
- The PI submitted the new research with animal protocol 1484 and it was approved on May 9, 2017.
- The PI submitted a new breeding protocol 1489 and it was approved on May 9, 2017.
- The IACUC concluded that the necessary steps have been completed by the PI and staff in her laboratory, ensuring that the University of Nebraska-Lincoln maintains the standards of animal care as outlined by the Animal Welfare Act (AWA) and the PHS Animal Welfare Policy, reinforced by UNL's NIH-approved Public Health Service Animal Welfare Assurance Document.

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

Sincerely,

(b) (6)

Debora L Hamernik, Ph.D.
Institutional Official
Interim Associate Vice Chancellor for Research

c: Interim Vice Chancellor for Research and Economic Development
IACUC Chair
Attending Veterinarian

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 11, 2017 3:36 PM
To: Kelly Heath; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Deb Hamernik
Subject: RE: A3459-01 Report of Non Compliance

Thank you Dr. Heath. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Kelly Heath [mailto:kheath3@unl.edu]
Sent: Thursday, May 11, 2017 1:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kelly Heath <kheath3@unl.edu>; Deb Hamernik <dhamernik2@unl.edu>
Subject: A3459-01 Report of Non Compliance

DearOLAW

Please find attached a final report of Non Compliance from the University of Nebraska Lincoln. This is in follow up to a telephone report to Dr. Wolff.

Please let me know if you have any questions.

Kind Regards,

Kelly



Kelly D Heath

Director and Attending Veterinarian

Institutional Animal Care Prog

1915 N. 38th Street

(b) (4) UNL, 68583-0720

University of Nebraska-Lincoln

Cell (b) (6)

Office: (b) (6)



Initial Report of Noncompliance

By: aw

Date: 4/26/17

Time: 11:00

Name of Person reporting: Dr. Kelly Heath

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: University of Nebraska-Lincoln

Assurance number: A3459

Did incident involve PHS funded activity? yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

5 mo mouse toe clipped w/out anesthesia for identification

Species involved: Mice

Personnel involved: Students

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Training, revise protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____