



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

March 13, 2017

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

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 March 2, 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. According to the information provided, OLAW understands that 20 rat pups were ear notched, although this activity was not described in the approved protocol. A graduate student had performed this activity without consulting the Principal Investigator (PI).

The corrective actions consisted of amending the protocol to include ear notching, retraining the PI and staff, and placing the laboratory under enhanced postapproval monitoring by the Institutional Animal Care and Use Committee.

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

March 2, 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 #997 Behavioral and Neuropharmacological Mechanisms of Antipsychotic Drugs

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:** 5 R03 HD079870-02
3. **Species:** Rat
4. **Effects on Programmatic or Physical Areas:** None
5. **Explanation of the Situation:**

History and background information: On Thursday, January 26, 2017 animal care staff identified that 20 rat pups on Protocol #997 had been ear notched. The animal care staff checked the protocol and was unable to determine if this activity was approved. They notified the Institutional Animal Care Program (IACP) office and inquired about this procedure. The IACP staff checked the protocol and determined that ear notching was not approved on the protocol. On Monday, January 30, 2017 the clinical veterinary staff met with the animal care staff to examine the animals and verified that they had been ear notched. The PI and his lab manager were contacted and instructed that this was an unapproved activity and no longer can be performed. As we worked through the issue with the PI it became clear that a graduate student had undertaken this off protocol activity without discussing it with the PI. The PI filed an amendment to his active protocols for IACUC review to add the ear notch procedure for genotyping.

6. Actions Taken by the IACUC:

The off protocol work was reported to the IACUC Institutional Official (Dr. Debora L. Hamernik, UNL Interim Associate Vice Chancellor of Research), and as required, the National Institutes of Health, Office of Laboratory Animal Welfare by telephone. The IACP staff conducted a 1.5 hour documented retraining with the PI and his laboratory staff on February 3, 2017. The Clinical Veterinarian also conducted a hands on training

for appropriate ear notching techniques with the laboratory staff on February 17, 2017. The off protocol work was reported and discussed at the February 14, 2017 IACUC meeting. The committee reviewed and approved the protocol amendments. The committee requested additional post approval monitoring of the PI and his lab.

7. Outcome:

- The PI and his staff have completed and documented the retraining provided by the IACP staff. Retraining was completed on February 3, 2017 and again on February 17, 2017.
- The post approval monitoring has been enhanced.
- The IACUC concluded that the necessary steps have been completed by the PI and laboratory staff, 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 any questions or require any further information, please do not hesitate to contact me.

Sincerely,

(b) (6)

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

c: Interim Vice Chancellor for Research
IACUC Chair
Attending Veterinarian

Gopee, Neera (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 03, 2017 12:20 PM
To: Kelly Heath; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Deb Hamernik; (b) (6)
Subject: RE: University Of Nebraska Report of Non-Compliance

Thank you for this final report Dr. Heath. We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Kelly Heath [mailto:kheath3@unl.edu]
Sent: Friday, March 03, 2017 10:33 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Deb Hamernik <dhamernik2@unl.edu>; (b) (6)
(b) (6)
Subject: University Of Nebraska Report of Non-Compliance

Dear Dr. Wolff

Please find attached our official of report of the off protocol work that I reported by telephone last month. Please let us know if you need any additional information.

Kind Regards,

Kelly



Kelly D Heath

Director and Attending Veterinarian

Institutional Animal Care Prog

1915 N. 38th Street

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University of Nebraska-Lincoln

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