



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

February 21, 2017

Re: Animal Welfare Assurance
#A3474-01 (OLAW Case Z)

Steven Schmidt, Ph.D.
Interim Vice President
and Dean for Research
Northeastern Ohio Universities College of Medicine
4209 State Route 44, P.O. Box 95
Rootstown, OH 44272-0095


Dear Dr. Schmidt,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 10, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Northeast Ohio Medical University (NEOMED). Your letter supplemented the information contained in an initial email report by condary individ to this office on September 29, 2016. According to the information provided, OLAW understands that on August 4, 2016 the desiccated carcass of a female big brown bat (*Eptesicus fuscus*) was found during the monthly change out of a flight cage by a research technician. The involved animal activity was funded by the NSF grant # NSF-CMMI 1537745.

Corrective actions proposed by the PI and approved by the IACUC included: 1) a requirement that two individuals inspect the cage and nest box at each monthly cage transfer 2) both individuals will sign-off on the Cage Change Protocol sheet once the transfer is complete, and 3) animals will be implanted with microchips and each animal will be scanned as they are transferred. In addition, the PI and research technician completed additional training in bat handling. It is also understood that costs related to this incident were not charged to the grant.

OLAW appreciates the prompt consideration of this matter by NEOMED, 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 and correct the deficiency, and to prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,


for Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Edda Thiels, NSF Animal Welfare Officer

January 10, 2017

Axel V. Wolfe, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982

RE: Animal Welfare Assurance #A-3474-01; Final Report
Granting Agency: National Science Foundation
Grant Number: NSF-CMMI 1537745
Current Program Director: David Fyhrie, Ph.D.

Dear Dr. Wolfe:

The Northeast Ohio Medical University (NEOMED), in accordance with Assurance #A-3747-01 and PHS Policy IV.F.3., provides this final report of a non-compliant event. PHS-related funds were involved in this incident.

A quorum of the NEOMED Institutional Animal Care and Use Committee (IACUC) met on August 16, 2016 to review a report of non-compliance involving the death of one female, big brown bat (*Eptesicus fuscus*). The IACUC learned that on August 4, 2016, a research technician reported finding a desiccated female bat below a clean flight cage when conducting the monthly cage change.

In response to the event, the IACUC sent a letter to the PI dated September 6, 2016 requesting development of an action plan to minimize the likelihood of recurrence and to formally submit the plan in writing to the IACUC. The PI provided a written action plan to the IACUC. The IACUC reviewed the plan as part of an overall review of the matter at a regular IACUC meeting on October 11, 2016. The Committee acknowledged the PI's letter to the IACUC outlining the incident, and unanimously requested additional information and changes to the submitted action plan. The IACUC approved the review and approval of the revised action plan via Designated Member Review (DMR).

The PI provided a revised action plan to the IACUC dated October 17, 2016. An IACUC sub-committee reviewed and approved the revised action plan via DMR. The IACUC was notified as part of another overall review of the matter at a regular IACUC meeting on November 8, 2016. The Committee acknowledged the PI's letter to the IACUC outlining the incident and unanimously agreed to accept the following revised action plan:

Action Plan: To prevent such incidents from occurring in the future, the PI implemented the following measures:

- 1) Two individuals are now required to inspect the flight cage and the nest box at the end of each monthly cage transfer. Both individuals will use a red light to illuminate the inside of the opaque nest box.
- 2) The investigator developed a *Eptesicus* Cage Change Protocol sheet. Both individuals conducting the change cage will sign off on this sheet once the transfer of animals is complete.
- 3) To further facilitate identification of the bats, animals will be injected with microchips. Animals will be scanned as they are transferred to a clean cage and their identification number checked.

Retraining: The PI and the research technician completed additional training in bat handling procedures on September 13, 2016. Documentation of this training is on file with the IACUC records.

The IACUC communicated to the PI, in writing on November 18, 2016, their acceptance of the above action plan.

The National Science Foundation was notified of the event on January 5, 2017. The animal housing costs related to this incident (\$3.30) was credited to the grant involved and was charged to an internal NEOMED account (non-federal source).

NEOMED is committed to protecting the welfare of animals used in research. Please contact me at [redacted telephone #] with any questions or concerns regarding this report.

Sincerely,



Steven P. Schmidt, Ph.D.
Interim Vice President for Research
NEOMED Institutional Official

SPS:lkn

Cc: Altaf Darvesh, Ph.D.
IACUC Co-Chair

Jesse W. Young, Ph.D.
IACUC Co-Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 23, 2017 8:22 AM
To: secondary individual
Subject: RE: Final Report

Thank you for this report, secondary individual. We will respond soon.

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

From: secondary individual [mailto:secondary individual@neomed.edu]
Sent: Thursday, January 19, 2017 2:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Report

RE: Northeast Ohio Medical University (NEOMED)
Animal Welfare Assurance #: A3474-01

To Whom It May Concern:

On behalf of Dr. Steven Schmidt, NEOMED Institutional Official (IO), and in accordance with Assurance #A3474-01 and PHS Policy IV.F.3, please find attached a PDF of our final report of non-compliance involving the death of a Big Brown bat.

Feel free to contact Dr. Schmidt by phone at telephone # or by e-mail at sschmidt@neomed.edu with any questions or concerns.

Thank you.

Secondary individual
 Regulatory Affairs Coordinator II

Secondary individual
 Regulatory Affairs Coordinator II
 Comparative Medicine Unit
 Northeast Ohio Medical University (NEOMED)

Northeast Ohio Medical University
 4209 St. Rt. 44 | PO Box 95 | Rootstown, Ohio 44272
 telephone # | telephone # | secondary individual@neomed.edu

[Website](#) | [Campus Map](#) | [Facebook](#) | [Twitter](#)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, October 03, 2016 9:24 AM
To: Secondary individual
Subject: RE: Non-Compliance Events - Preliminary Reports

Thank you for this report. Secondary individual will open a case file and await your final report.

Sincerely, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Secondary individual [mailto:Secondary individual@neomed.edu]
Sent: Thursday, September 29, 2016 7:57 AM
To: Morse, Brent (NIH/OD) [E]
Subject: Non-Compliance Events - Preliminary Reports

RE: Northeast Ohio Medical University
 Animal Welfare Assurance #: A3474-01

Good Morning Dr. Morse!

not this case

I hope this finds you doing well today! The Northeast Ohio Medical University (NEOMED) wishes to inform you of two issues the IACUC deemed to be reportable. The first involved the death of two newly weaned mice. This event involved PHS funds. The second event involved the death of a bat. This event involved NSF funds.

Final reports will be forwarded to OLAW as the IACUC addresses each event. The reports will also contain the name of the funding agency, the grant award number, and the name of the current program officer.

Feel free to contact me with any questions or concerns, or if there is any additional information that we need to include in each final report.

Have a great day and a wonderful weekend!

Secondary individual



[REDACTED]
Regulatory Affairs Coordinator II
Comparative Medicine Unit
Northeast Ohio Medical University (NEOMED)

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