



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
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) 402-7065

July 9, 2019

Re: Animal Welfare Assurance
#A3474-01 (OLAW Case 1C)

Steven Schmidt, Ph.D.
Vice President 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 July 3, 2019 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 telephone report to this office on April 29, 2019. According to the information provided, OLAW understands that outdated Fatal Plus was used to euthanize an anesthetized piglet at the study endpoint. There was no signs of pain or distress with the animal. The involved animal activity was funded by the NICHD grant # R01HD088561.

Corrective actions proposed by the PI and accepted by the IACUC included: 1) only small aliquots of controlled substances will be obtained by the lab from the Comparative Medicine Unit; 2) the expiration date will be checked and the correct drug and dosage will be double checked before each administration, and; 3) all of the investigator's drugs and expiration dates will be placed on the lab electronic calendar to prevent them being kept past the expiration date. Also, the PI and research staff who conduct animal euthanasia completed additional training in controlled substances and the investigator completed an applicable CITI training module. 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,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC



July 3, 2019

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892

**RE: Northeast Ohio Medical University
Animal Welfare Assurance #A-3474-01; Final Report**

**Granting Agency: National Institute of Health - NICHD
Grant Number: NIH-NICHD #R01HD088561
Current Program Director: Marie Hosso-Thomas, Ph.D.**

Dear Dr. Morse:

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. A preliminary report was provided to you by phone. PHS-related funds were involved in this incident.

A quorum of the NEOMED Institutional Animal Care and Use Committee (IACUC) reviewed a report of non-compliance on April 16, 2019 involving the euthanasia of one piglet at study endpoint with outdated Fatal Plus. The Fatal Plus was outdated by approximately three weeks. The animal was under a surgical plane of anesthesia at the time of euthanasia. When the Fatal Plus was administered to euthanize the piglet, the animal experienced a normal death. The IACUC voted this was a reportable, non-compliance.

In response to the event, the IACUC sent a letter to the PI on April 19, 2019 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 convened IACUC meeting on May 21, 2019.

The Committee acknowledged the PI's letter to the IACUC outlining the incident and unanimously voted to accept the following action plan:

Action Plan:

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

- 1) All drugs in the investigator's possession and their expiration dates are now listed on the lab's online calendar, which all members of the research team have access to. This ensures that each individual can take responsibility that drugs are not being kept past their expiration dates. The drugs will be disposed of properly when their expiration is met.
- 2) Controlled substances will no longer be kept in the lab's drug cabinet, but rather will be purchased, as needed, in small aliquots from the Comparative Medicine Unit.
- 3) The lab is emphasizing that before giving any injection, it will be their standard operating procedure to check not only the expiration date on a drug label, but they will also double check it is the correct drug and correct dosage prior to administering to an animal.

Retraining:

- 1) The investigator completed the CITI "Biomedical Responsible Conduct of Research" module on May 6, 2019.
- 2) The investigator and those members of the research team who euthanize animals underwent re-training in the use of controlled substances on May 2, 2019. The training was conducted by the NEOMED Certifying Official / Attending Veterinarian.

Documentation of the above training is on file with the IACUC records.

The IACUC communicated to the PI, in writing on June 6, 2019, their acceptance of the above action plan.

The National Institutes of Health was notified of the event, via e-mail, on June 26, 2019. The costs related to this incident (\$293.01) was credited to the grant involved and was subsequently charged to an internal NEOMED account (non-federal source) on June 25, 2019.

NEOMED is committed to protecting the welfare of animals used in research. Please contact me at (b) (6) with any questions or concerns regarding this report.

Sincerely,

(b) (6)

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

SPS:lkn

Cc: Jesse W. Young, Ph.D.
IACUC Chair

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 05, 2019 2:53 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Steven Schmidt; Jesse Young; (b) (6)
Subject: RE: Final Report to OLAW (#A3474-01)

Thank you for providing this final report (b) (6). We will send an official response soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Friday, July 05, 2019 2:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Steven Schmidt <:sschmidt@neomed.edu>; Jesse Young <jwyoung@neomed.edu>; (b) (6)
(b) (6)
Subject: Final Report to OLAW (#A3474-01)

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 our Animal Welfare Assurance #A3474-01 and PHS Policy IV.F.3, please find attached a PDF of our Final Report of non-compliance that involved euthanasia of one piglet with outdated Fatal Plus.

Feel free to contact Dr. Schmidt by phone at (b) (6) or by e-mail at sschmidt@neomed.edu with any questions or concerns.

Thank you.

(b) (6)

(b) (6)



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Initial Report of Noncompliance

By: *[Signature]*

Date: 4/29/19

Time: 8:10

Name of Person reporting: (b) (6)

Telephone #:

Fax #:

Email:

Name of Institution: NEOMED

Assurance number: A3474

Did incident involve PHS funded activity?

Funding component:

Was funding component contacted (if necessary):

What happened?

PI euthanized piglet 3 weeks post end of protocol. No animal welfare issues.

Species involved: Sus scrofa

Personnel involved: PI

Dates and times:

Animal deaths:

Other animals still on study. I told them to contact Chief GMO.

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

Projected submission to OLAW of final report from Institutional Official:

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Case #