



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

October 13, 2017

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

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 October 2, 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 telephone report to this office on August 24, 2017. According to the information provided, OLAW understands that outdated Nembutal was used to anesthetize mice as part of a terminal procedure. There was no signs of pain or distress with the animals. The involved animal activity was funded by the NIGMS grant # 5R01GM112044-03.

Corrective actions proposed by the PI and accepted by the IACUC included: 1) only small aliquots of anesthetic will be obtained by the lab; 2) the expiration date will be checked and recorded before each experiment, and; 3) a reminder will be placed on the lab electronic calendar with a reminder two weeks before the expiration date. Also, the PI and research staff completed additional training in controlled substances and in rodent anesthesia/euthanasia. 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,

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

cc: IACUC contact
Grace Olascoaga, Chief Grants Management Officer, NIGMS



October 2, 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 Institute of Health - NIGMS
Grant Number: NIH-NIGMS #5R01GM112044-03
Current Program Director: Veerasamy Ravichandran, Ph.D.

Dear Dr. Wolfe:

The Northeast Ohio Medical University (NEOMED), in accordance with Assurance #A-³⁴⁷⁴~~3474~~-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) reviewed a report of non-compliance involving the use of outdated Nembutal to anesthetize mice as part of a terminal procedure. The investigator reported when the Nembutal was administered to the mice, the animals did not show signs of pain and/or distress or experience anything unusual.

In response to the event, the IACUC sent a letter to the PI 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.

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) Small aliquots of anesthesia will be acquired from the Comparative Medicine Unit.
- 2) The expiration date of the anesthetic will be checked and recorded prior to each experiment.
- 3) A reminder will be placed in the lab's electronic calendar with a 2-week advance notice of the drug's expiration date.

Retraining: The PI and his research staff completed additional training in controlled substances and in rodent anesthesia/euthanasia. This training was conducted by the Attending Veterinarian. Documentation of this training is on file with the IACUC records.

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

October 2, 2017
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The National Institutes of Health was notified of the event on September 29, 2017. The animal housing and related costs to this incident (\$10.40) 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.
Vice President for Research
NEOMED Institutional Official

SPS:lk

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

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

Morse, Brent (NIH/OD) [E]

From: Ravichandran, Veerasamy (NIH/NIGMS) [E]
Sent: Friday, September 29, 2017 12:08 PM
To: Lynch, Jennifer (NIH/NIGMS) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: FW: Non-Compliant Event/Repayment of Grant

Hi Jennifer,

Could you please upload this email on to this PI's grants folder?

Thanks,

Ravi

*Veerasamy "Ravi" Ravichandran, Ph.D.
 Program Director
 Biomedical Technology, Bioinformatics and Computational Biology Division
 National Institute of General Medical Sciences
 National Institutes of Health, Bld 45, Room 2AN12M
 45 Center Drive, MSC 6200
 Bethesda, Maryland 20892-6200
 301-451-9822 (phone)
 301-480-0884 (fax)
Veerasamy.Ravichandra@nih.gov*

From: Secondary Individual [mailto:Secondary Individual@neomed.edu]
Sent: Friday, September 29, 2017 9:08 AM
To: Ravichandran, Veerasamy (NIH/NIGMS) [E] <veerasamy.ravichandra@nih.gov>
Cc: Steven Schmidt <sschmidt@neomed.edu>; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyong@neomed.edu>; Secondary Individual [mailto:Secondary Individual@neomed.edu]
Subject: Non-Compliant Event/Repayment of Grant

NOTE: This e-memo is being submitted on behalf of Dr. Steven Schmidt, NEOMED Institutional Official

RE: Northeast Ohio Medical University
 National Institutes of Health, NIGMS: #5R01GM112044-03
 Secondary Individual

Dear Dr. Ravichandran:

Recently the Northeast Ohio Medical University (NEOMED) experienced an animal use non-compliant event involving NIH-NIGMS funds. Outdated Nembutal was used to anesthetize mice as part of a

terminal procedure. Appropriate notification of the event is being provided to the Office of Laboratory Animal Welfare (OLAW).

The animal use protocol under which the animal was used is supported by NIH-NIGMS Award #5R01GM112044-03. The costs associated with this activity that were charged to the award (\$10.40) have been credited to the grant and were subsequently covered by a non-federal source. All animal work related to NIH-NIGMS Award #5R01GM112044-03 has been approved by this institution's IACUC and is continuing.

Feel free to contact me by phone at [redacted telephone #] or by e-mail at sschmidt@neomed.edu with any questions or concerns or if additional information is needed.

Steven P. Schmidt, Ph.D.
NEOMED Institutional Official

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
v [redacted phone Number] f [redacted phone Number] e [redacted email]@neomed.edu

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



Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 03, 2017 1:27 PM
To: Secondary Individual OLAW Division of Compliance Oversight (NIH/OD)
Cc: Steven Schmidt; Secondary Individual Altaf Darvesh; Jesse Young
Subject: RE: Final Report to OLAW (#A3474-01)

Thank you for sending this report. We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting Director
 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: Tuesday, October 03, 2017 11:18 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Steven Schmidt <sschmidt@neomed.edu>; Secondary Individual@neomed.edu; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyong@neomed.edu>
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 cervical dislocation of conscious mice without IACUC approval.

Feel free to contact Dr. Schmidt by phone at Secondary Individual 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)

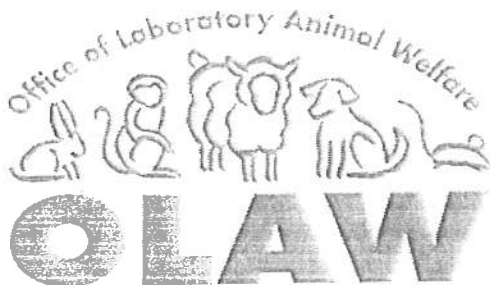
Northeast Ohio Medical University

4209 St. Rt. 44 | PO Box 95 | Rootstown, Ohio 44272

Phone Number Phone Number e ryl@neomed.edu

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





Initial Report of Noncompliance

By: gmmDate: 8/24/17Time: 4:15 (Voicemail)

Name of Person reporting:

Secondary Individual

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution:

NEOMED

Assurance number:

A3474Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Mice given outdated Nembutal.Species involved: MicePersonnel involved: Researcher

Dates and times: _____

Animal deaths: _____

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____