



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

December 7, 2017

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

Steven Schmidt, Ph.D.
Vice President for Research
Northeastern Ohio Medical University
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 November 22, 2017 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) at Northeast Ohio Medical University (NEOMED) which was preceded by a preliminary report to OLAW via telephone on August 24, 2017. Additional information was also provided via email on December 7, 2017 after OLAW requested clarification to the submitted letter. According to the information supplied, OLAW understands that the IACUC reviewed a report involving 79 mice that were euthanized using a method that was not an IACUC-approved method. The involved animal activity was PHS supported by NIH National Institute on Alcohol Abuse and Alcoholism (NIAAA) grants 5R01AA015951-12 and 5R01AA013623-15. The funding agency was notified of this incident.

The corrective actions included a response from the principal investigator (PI) indicating that the approved protocol with IACUC-approved methods of euthanasia would be followed. Additionally, retraining was completed both online and in person by the PI and laboratory staff.

OLAW believes that the described corrective actions are appropriate to reduce the likelihood of recurrence of this noncompliance. Thank you for your commitment to protecting the welfare of animals in research and your compliance with the PHS Policy and NEOMED Animal Welfare Assurance. Please note that reports of noncompliance to OLAW should include dates of occurrence when describing the incident and we request that this information be provided in future submissions from your institution. We appreciate being informed of these matters and find no cause for further action by this Office at this time.

Sincerely,

Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact
NIH NIAAA Chief Grants Management Officer
NIH NIAAA Program Director
NIH NIAAA Grants Management Specialist

Secondary Individual

Secondary Individual

Phone Number Phone Number ry I

Secondary Individual

ary In

Na, Jane (NIH/OD) [E]

From: Winston, Milli (NIH/NIAAA) [E]
Sent: Wednesday, December 06, 2017 10:47 AM
To: Morse, Brent (NIH/OD) [E]
Cc: Fox, Judy (NIH/NIAAA) [E]; Na, Jane (NIH/OD) [E]; Winston, Milli (NIH/NIAAA) [E]; Gao, Peter (NIH/NIAAA) [E]
Subject: RE: Non-Compliant Event/Repayment of Grant
Expires: Sunday, February 04, 2018 12:00 AM

Dear Dr. Morse,

Thank you very much for this resolution to this incident of non-compliant event/repayment.

Our records will be uploaded to reflect all communications regarding the closure.

Sincerely,
Milli

Milli Winston | Grants Management Specialist
Phone: 301-443-5173
Email: mwinston@mail.nih.gov

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, December 06, 2017 9:57 AM
To: Winston, Milli (NIH/NIAAA) [E] <mwinston@willco.niaaa.nih.gov>
Cc: Fox, Judy (NIH/NIAAA) [E] <jfox@mail.nih.gov>; Na, Jane (NIH/OD) [E] <jane.na@nih.gov>
Subject: RE: Non-Compliant Event/Repayment of Grant

Good morning Ms. Winston,

Our office has received the final report from NEOMED concerning this incident. We will be accepting their report, including their corrective measures and sending them an acceptance letter soon. We will copy you on that letter. The institution has fulfilled their requirements under the PHS Policy on Humane Care and Use of Laboratory Animals and Notice # NOT-OD-10-081 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html>. In consideration of the small monetary consequence, further effort regarding this case should be limited unless the institution has other reasons for requesting a conference call. Please let me know if I can be of further assistance.

Sincerely, 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.

Secondary Individual

ary In

From: Secondary Individual (mailto:Secondary Individual@neomed.edu)

Sent: Monday, December 04, 2017 2:32 PM

To: Gao, Peter (NIH/NIAAA) [E] <gaozh@mail.nih.gov>

Cc: Steven Schmidt <sschmidt@neomed.edu>; Secondary Individual @neomed.edu; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyoung@neomed.edu>; Secondary Individual @neomed.edu

Subject: RE: Non-Compliant Event/Repayment of Grant

Hi, Dr. Gao!

Thank you for letting me know! Below is an overview of the non-compliant event:

- Whistleblower verbally reported to an IACUC member their observation of conscious mice being cervically dislocated within a laminar fume hood in an animal housing room (not an approved method in the protocol); No observation of a euthanasia chamber or CO₂ tank were present in the room where the dislocations were taking place.
- IACUC sub-committee conducted a preliminary meeting with the Investigator and their research team to inform them of the whistleblower report.
- IACUC investigated the matter and conveyed the outcome to the Investigator at two convened IACUC meetings. The Investigator provided no additional information at either meeting.
- IACUC voted that a non-compliant event had occurred and that it was reportable to OLAW, AAALAC International, and the granting agency.
- Investigator notified in writing of the IACUCs decision regarding the matter and the resulting required actions steps (Submission of an Action Plan; Retraining of the Investigator and those on the research team responsible for euthanizing mice; Funding Agency information).
- IACUC received, reviewed and voted to accept the Investigator's Action Plan; All required retraining was completed by the Investigator and those members of the research team responsible for euthanizing mice; Funding agency information was provided to include with OLAW Final Report and for grant repayment.
- Grants repaid; Final Report sent to OLAW; Report sent to AAALAC International.
- IACUC considers this matter closed unless deemed otherwise by OLAW or AAALAC International.

We hope this information is helpful! Feel free to contact Dr. Steven Schmidt, NEOMED Institutional Official, with any questions or if additional information is needed. Dr. Schmidt is currently out of the office and will return on Thursday, 12/07/17.

Enjoy the rest of your day!

Secondary Individual

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



From: Gao, Peter (NIH/NIAAA) [E] [\[mailto:gaozh@mail.nih.gov\]](mailto:gaozh@mail.nih.gov)
Sent: Thursday, November 30, 2017 5:19 PM
To: [Secondary Individual@neomed.edu](mailto:[redacted]@neomed.edu)>
Subject: RE: Non-Compliant Event/Repayment of Grant

[redacted] ary In

Can you send me more information about this non-compliant event, such as when , where and what exactly happened. I need to know this information before involving other related members in NIAAA for this meeting.

Best regards

Peter

Zhigang (Peter) Gao, MD.

Program Director
Division of Metabolism and Health Effects
National Institute on Alcohol Abuse and Alcoholism, NIH
5635 Fishers Lane, Room 2035
Rockville, MD 20852
Tel: 301-443-6106
Fax: 301-594-0673
Email: gaozh@mail.nih.gov

From: [\[redacted\] ary In@neomed.edu](mailto:[redacted]@neomed.edu)
Sent: Thursday, November 30, 2017 4:43 PM
To: Gao, Peter (NIH/NIAAA) [E] <gaozh@mail.nih.gov>
Cc: Steven Schmidt <sschmidt@neomed.edu>; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyong@neomed.edu>
Subject: RE: Non-Compliant Event/Repayment of Grant

Hi, Dr. Gao!

Dr. Schmidt, our Institutional Official, is currently out of the country and will not be returning until 12/07/17. In the meantime, the IACUC Co-Chairs, the Attending Veterinarian and I would like to schedule a conference call with you to discuss this matter. Can you let me know your availability over the next several days so that we may schedule a mutually agreeable time for the call? Thank you in advance.

Enjoy the rest of your day!

[Secondary Individual](mailto:[redacted]@neomed.edu)

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]hone Number | f [redacted]hone Number | e [redacted]ry.j@neomed.edu

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



From: Gao, Peter (NIH/NIAAA) [E] [<mailto:gaozh@mail.nih.gov>]

Sent: Wednesday, November 22, 2017 12:30 PM

To: [redacted]Secondary Individual@neomed.edu>

Cc: Steven Schmidt <sschmidt@neomed.edu>; [redacted]Secondary Individual@neomed.edu>; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyoung@neomed.edu>

Subject: RE: Non-Compliant Event/Repayment of Grant

Dr. Schmidt,

Thank you for letting us know this non-compliant animal use event.

I expect to see a more detailed report of this event after your investigation. The PI is also required to report this event, including all related documents, in the annual progress report to NIAAA.

Thank you.

Peter Gao

Zhigang (Peter) Gao, MD.

Program Director
Division of Metabolism and Health Effects
National Institute on Alcohol Abuse and Alcoholism, NIH
5635 Fishers Lane, Room 2035
Rockville, MD 20852
Tel: 301-443-6106
Fax: 301-594-0673
Email: gaozh@mail.nih.gov

From: [redacted]Secondary Individual (mailto:[redacted]ary Ir@neomed.edu]

Sent: Wednesday, November 22, 2017 8:58 AM

To: Gao, Peter (NIH/NIAAA) [E] <gaozh@mail.nih.gov>

Cc: Steven Schmidt <sschmidt@neomed.edu>; [redacted]Secondary Individual@neomed.edu>; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyoung@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

November 22, 2017

RE: Northeast Ohio Medical University
National Institutes of Health; NIAAA Grants:
Award #5R01AA015951-12
Award #5R01AA013623-15
Investigator Name: Min You, Ph.D.

Dear Dr. Gao:

Recently the Northeast Ohio Medical University (NEOMED) experienced an animal use non-compliance event involving NIH-NIAAA funds. Conscious mice were euthanized via cervical dislocation. Appropriate notification of the event is being provided to the Office of Laboratory Animal Welfare (OLAW).

The animal use protocol under which the animals were used is supported by NIH-NIAAA Award #5R01AA015951-12 and by Award #5R01AA013623-15. The costs associated with this activity that were charged to each award (\$2.90/award) were credited to the grants and were subsequently covered by a non-federal source. All animal work related to NIH-NIAAA Award #5R01AA015951-12 and Award #5R01AA013623-15 has been approved by this institution's IACUC and is continuing.

Feel free to contact me by phone at [Phone Number] 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 [Phone Number] | f [Phone Number] | e rv@neomed.edu

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





Northeast Ohio

MEDICAL UNIVERSITY

November 22, 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 - NIAAA
Grant Numbers: NIH-NIAAA #5R01AA015951-12 and NIH-NIAAA #5R01AA013623-15
Current Program Director: Zhigang (Peter) Gao, M.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) reviewed a report of non-compliance involving 79 conscious mice euthanized via cervical dislocation, which is not an IACUC approved method of euthanasia for the protocol. The IACUC voted this was a reportable, non-compliance.

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) The investigator reiterated their instructions to lab personnel to document their animal experiments rigorously with details to prevent such events in the future.
- 2) The investigator declined the IACUC's suggestion to amend the protocol to include cervical dislocation without anesthesia as an additional method of euthanasia and to provide a scientific justification. The investigator indicated, "...no changes/amendments are necessary scientifically. Animal studies in my laboratory have been and will continue to use the approved protocol."

Retraining: The PI and their research staff completed additional web-based training in the AALAS Learning Library. The completed modules included: "Working with the IACUC"; "Common Compliance Issues", and "Introduction to Mice". Additional training in mouse euthanasia (cervical dislocation) and an overview of compliance was completed with the Attending Veterinarian. Documentation of all training is on file with the IACUC records.

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

November 22, 2017
Page 22

The National Institutes of Health was notified of the event on November 22, 2017. The animal housing costs related to this incident (\$580 total = \$290/grant) were credited to the two grants involved and subsequently 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 330.325.6465 with any questions or concerns regarding this report.

Sincerely,



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

SPS:kk

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: Wednesday, November 22, 2017 10:31 AM
To: [REDACTED]
Subject: RE: Final Report to OLAW (#A3474-01)

Thank you for this report, [REDACTED]. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: [REDACTED] [mailto:[REDACTED]@neomed.edu]
Sent: Wednesday, November 22, 2017 10:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Steven Schmidt <sschmidt@neomed.edu>; [REDACTED] <[REDACTED]@neomed.edu>; Altaf Darvesh <adarvesh@neomed.edu>; Jesse Young <jwyoung@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 [REDACTED] or by e-mail at sschmidt@neomed.edu with any questions or concerns.

Thank you.

[REDACTED]

Regulatory Affairs Coordinator II

[REDACTED]

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] | f[REDACTED] | e[REDACTED]@neomed.edu

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



Initial Report of Noncompliance

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

Name of Person reporting:

Secondary Individual

Telephone #:

Fax #:

Phone Number

Email:

Name of Institution:

NEOMED

Assurance number:

A3474Did incident involve PHS funded activity? ?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Mice underwent crw. disloc. w/o anesthesia.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 # _____



Division of Compliance Oversight

Record of Call for Case # A3474-1A

Date & Time	Message	Initials
11/17/17 3:31	Left V/m for requesting update Secondary Individual	<i>[Signature]</i>