



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

May 7, 2018

Re: Animal Welfare Assurance
A3381-01 [OLAW Case 2B]

Dr. Jennifer K. Lodge
Vice Chancellor for Research
Washington University in St. Louis
660 South Euclid Ave., Box 8108
St. Louis, MO 63130

Dear Dr. Lodge,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Washington University in St. Louis, following up on an initial telephone report on April 10, 2018. According to the information provided, OLAW understands that 24 mice on a cecal ligation and puncture surgery failed to receive one of the required post-operative analgesics and several failed to receive the long acting or full dose of another analgesic. No adverse clinical signs were reported in the mice.

The corrective actions consisted of retraining the Principal Investigator and staff, ensuring that analgesics will be given as stated in the protocol, and amending the protocol to include additional analgesic regimens.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Institutional Animal Care and Use Committee

April 16, 2018

Assurance: D16-00245 (A3381-01)

Dr. Axel Wolff, DVM, MS

Deputy Director, Office of Laboratory Animal Welfare

National Institutes of Health

Rockledge Drive

Bethesda, MD 20892-7982

Initial Report: April 10, 2018

Protocol: 20170124 "Circadian regulation of oxidative stress and neurodegeneration"

Dear Dr. Wolff,

Washington University in St. Louis (WU), in accordance with PHS Policy IV.F.3 and Assurance D16-00245, submits this final report for a non-compliant event initially reported by the IACUC Director on April 10, 2018.

During a post-approval monitoring visit and surgery records review, inspectors identified noncompliance with the approved post-operative analgesic regimen in approximately 24 mice. Mice were approved to receive Buprenorphine SR and Meloxicam following cecal ligation and puncture surgery. None of the 24 mice received meloxicam and a subset of the mice received a standard formulation of the buprenorphine. The standard buprenorphine was administered once a day (as approved in the protocol for other procedures) and not twice a day (as recommended). The animals were observed post-operatively as described in the protocol and no additional adverse clinical consequences were reported for those animals with the altered analgesic administration.

In response, the lab and PI completed retraining with members of the Quality Assurance/Quality Improvement staff and provided assurances that analgesics would be administered as described in the protocol for all future procedures. An amendment to update the analgesic options was reviewed and approved by the IACUC. The incident and completed corrective actions were reviewed by the IACUC at a convened meeting and the committee considers the incident resolved.

The protocol associated with the noncompliance was supported by NIH funding (5K08NS079405 and R01AG054517) but no specific costs were determined to be associated with the incident. In accordance with NIH Grants policy, any NIH funds directly associated with noncompliant events would be returned.

Please let me know if you have any questions or would like additional information.

Sincerely,

(b) (6)

Jennifer K. Lodge, Ph.D.

Institutional Official

Vice Chancellor for Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 04, 2018 7:01 AM
To: 'Moore, Meredith'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00245 (A3381-01) Final Reports

Thank you for these reports, Dr. Moore. We'll send responses soon.
 Axel Wolff

From: Moore, Meredith [mailto:moore577@wustl.edu]
Sent: Thursday, May 03, 2018 2:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Lodge, Jennifer <lodgejk@wustl.edu>;
 (b) (6) Moore, Meredith <moore577@wustl.edu>
Cc: accredit@aaalac.org; (b) (6)
 (b) (6)
Subject: D16-00245 (A3381-01) Final Reports

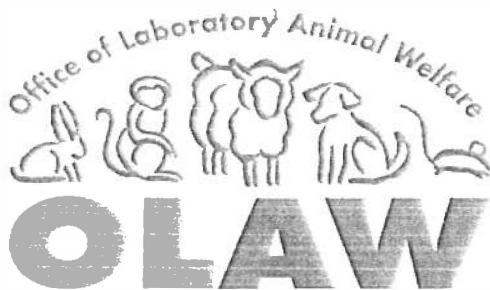
Dr. Wolff,

Attached, please find two final reports for separate incidents at Washington University at St. Louis initially reported April 10, 2018. Our Assurance number is D16-00245 (A3381-01).

If you have any questions, please let me know.

Meredith L. Moore, PhD, CPIA
 Director, IACUC Office
 Washington University in St. Louis
 (b) (6)

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.



Initial Report of Noncompliance

By: awDate: 9/10/18Time: 21:00Name of Person reporting: Meredith MooreTelephone #: (b) (6)

Fax #:

Email:

Name of Institution: Washington U St LouisAssurance number: A3381Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Cecal ligation + puncture 24 mice did not get analgesic,
others did not get long acting analgesic, did not get full dose

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

PI + lab retained, will give drugs per protocol,
Amend protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____