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

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May 7, 2018

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

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 28 mice received a trocar pellet implant but were not given analgesia as stated in the protocol. No signs of pain or adverse events were noted with the mice.

The corrective actions consisted of retraining the Principal Investigator and staff, having the laboratory ensure that analgesics will be given, reviewing the content of the protocol, and amending the protocol.

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

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Washington University in St. Louis
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: 20160289 "Metabolism-Excitation Control of Smooth Muscle Function and Pathology"

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 28 mice. Mice were approved to receive carprofen after a minor procedure (trocar pellet implant). None of the mice received the carprofen. The animals were observed post-operatively as described in the protocol and no signs of pain or other adverse clinical consequences were observed.

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. The PI will amend the protocol before making changes to the analgesic regimen and has reviewed the approved protocol with the surgeons. Both surgeons involved in the incident will complete the rodent surgery wet lab course as part of their retraining. The IACUC reviewed the incident at a convened meeting and the committee determined that the proposed corrective action plan was appropriate.

The protocol associated with the noncompliance was supported by NIH funding (HL09501009, DK1094070, HL14002401) 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,

[redacted] (b) (6)

Jennifer K. Lodge, Ph.D.
Institutional Official
Vice Chancellor for Research

Campus Box 1054, One Brookings Drive, St. Louis, MO 63130
(314)362-3229, *Fax* (314)747-6695, http:asc.wustl.edu

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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)

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A3381-2A

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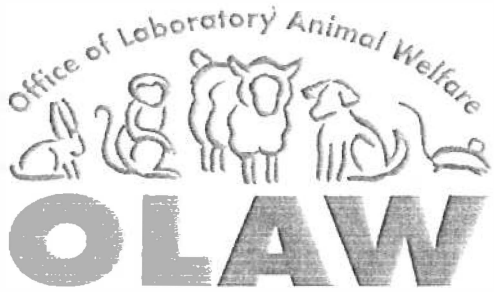

Initial Report of Noncompliance

By: [illegible]

Date: 4/10/18

Time: 8:00

Name of Person reporting: [illegible]
Telephone #: [redacted] (b) (6)
Fax #:
Email:

Name of Institution: Washington U St Louis
Assurance number: A3381

Did incident involve PHS funded activity? YES
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

No analgesic given after pellet implant to 28 mice. No pain noted. 1 person not trained.

Species involved: mouse
Personnel involved:
Dates and times:
Animal deaths:

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

Retrain PI + lab staff

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____