DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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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

June 18, 2018

Re: Animal Welfare Assurance
A3381-01 [OLAW Case 1Z]

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 June 12, 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 post-operative monitoring records were incomplete for fifty mice. Monitoring had been conducted and no problems were noticed with the mice, but it had not been recorded.

The corrective actions consisted of retraining the surgeon who agreed to appropriately document all post-operative monitoring.

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,

[redacted] (b) (6)

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

cc: IACUC Chair
Meredith Moore, Ph.D., IACUC Director

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Washington University in St. Louis
Institutional Animal Care and Use Committee

June 12, 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: #20150043 "Molecular Mechanisms Regulating Axon Maintenance"

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 incomplete documentation of post-operative monitoring in approximately fifty mice. Post-operative monitoring had been completed as described in the protocol and no adverse clinical consequences were observed. The surgeon thought the documentation was only required in the event of a complication.

In response, the surgeon completed retraining with members of the Quality Assurance/Quality Improvement staff and provided assurances that all post-operative monitoring activities would be appropriately documented. The incident and completed corrective actions were reviewed by the IACUC at the April 24, 2018 meeting and the committee considers the incident resolved.

The protocol is supported by NIH funding (R01 CA21986601, R01 NS06505308, and R21 NS087562) 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:	Thursday, June 14, 2018 6:11 AM
To:	Moore, Meredith
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Final Reports

Thank you for these reports. We will respond soon.
Axel Wolff

From: Moore, Meredith [mailto:moore577@wustl.edu]
Sent: Wednesday, June 13, 2018 5:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Moore, Meredith <moore577@wustl.edu>; [redacted] (b) (6) Lodge, Jennifer <lodgejk@wustl.edu>; [redacted] (b) (6)
Cc: accredit@aaalac.org
Subject: Final Reports

Dr. Wolff,

Attached, please find two final reports for incidents initially reported April 10, 2018.
Please contact me if you have any additional questions or comments.

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

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A3381-12

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: aw

Date: 4/10/18 Time: 2:00

Name of Person reporting: Meredith Moore
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?
50 mice - no record of post-op monitoring,
Did give carprofen analgesic + was documented

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

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

Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____

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