

**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

April 12, 2018

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive Bethesda, Maryland 20817 Teleghone: (301) 496-7163 Facsimile: (301) 402-7065

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

Dr. Jennifer Lodge Associate Dean for Research Washington University – St. Louis 660 South Euclid Avenue, Box 8108 St. Louis, Missouri 63110

Dear Dr. Lodge,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 23, 2018 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Washington University in St. Louis. According to the information provided, OLAW understands that an investigator's protocol was suspended by the IACUC due to repeated noncompliance. Specifically, the administration of expired anesthetic agents to mice on four separate occasions. In addition, a surgeon performed surgery before completing a previously imposed corrective action plan and receiving official notification from the IACUC allowing her to perform surgery. This research is supported by two NIDDK grants (5DK070790-12 and 4R01DK089137-05)

The corrective actions consisted of the IACUC requiring the PI to meet with the IACUC Chair and Director to discuss the incident and plans for future oversight of the lab. The lab attended a retraining session with the QA/QI staff and the PI has appointed a Point of Contact for the lab. A protocol amendment was approved on March 7 and the suspension lifted.

OLAW believes that the corrective measures put in place by Washington University in St. Louis are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. OLAW appreciates being informed of this issue and finds no cause for further action by this office.

Sincerely,

(b) (6)

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

## Washington University in St. Louis

## Institutional Animal Care and Use Committee

Brent Morse, DVM, Acting Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982 March 23, 2018 Assurance #A3381-01

Re: Protocol title: "Mouse studies in chronic kidney disease (CKD)"; supported by PHS/NIH funds (grant numbers 5DK07079012 and 4R01DK08913705)

Dr. Morse,

Washington University in St. Louis (WU) in accordance with Assurance A3381-01 and PHS Policy IV.F.3., is submitting a final report for the incident reported March 6, 2018.

The investigator's protocol was suspended following administration of expired anesthetic agents to mice on four separate occasions. In addition, a surgeon returned to work before all elements of a previously imposed corrective action plan could be completed.

In response, the IACUC required the PI to meet with the IACUC Chair and IACUC Director to discuss the incident and plans for future oversight of the lab. The lab attended a retraining session with the QA/QI staff and reviewed applicable regulations and policies. The PI has appointed a Point of Contact (POC) for the lab and the individual has reviewed the list of responsibilities associated with the designation. The amendment to update the protocol was approved on March 7, 2018.

The suspension was lifted on March 7, 2018 following completion of the required corrective actions.

Colony maintenance expenses accrued during the suspension will not be charged to the NIH grants supporting the protocol unless permitted by the NIH funding component.

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

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Sincerely,

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

C: AAALAC, International

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

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## Morse, Brent (NIH/OD) [E]

From: Sent:	OLAW Division of Compliance Oversight (NIH/OD) Tuesday, April 10, 2018 3:06 PM		
To:	Moore, Meredith; OLAW Division of Compliance Oversight (NIH/OD)		
Cc:	Lodge, Jennifer;		
	(b) (6)		
Subject:	RE: Final Report		

Thank you for this final report Dr. Moore. 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

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From: Moore, Meredith [mailto:moore577@wustl.edu]		
Sent: Tuesday, April 10, 2018 1:15 PM		
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>		
Cc: Lodge, Jennifer <lodgejk@wustl.edu>;</lodgejk@wustl.edu>	(b) (6)	
<sup>(b) (6)</sup> Moore, Meredith <moore577@wustl.edu>;</moore577@wustl.edu>		(b) (6)
(b) (6) accredit@aaalac.org;	(b) (6)	
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Subject: Final Report

OLAW,

Attached, please find our final report for the incident initially reported March 6, 2018. Please let me know if you have any comments or questions.

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

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## Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)	
Sent:	Thursday, March 08, 2018 8:29 AM	
To:	IACUC; OLAW Division of Compliance Oversight (NIH/OD)	
Cc: Subject:		(6)

Thank you for this prompt report. We will consider this a <u>preliminary report</u> and open a compliance case file. Since this is an NIH-funded activity, please notify the NIH funding component of the suspension and be sure to not use grant funds during the suspension period unless specifically allowed to do so by the funding component for husbandry or veterinary support only. Please notify OLAW by separate signed letter when the corrective measures have been completed. Thank you again.

Regards, Brent Morse

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

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From: IACUC [mailto:IACUC@wustl.edu] Sent: Wednesday, March 07, 2018 4:21 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: Lodge, Jennifer <lodgejk@wustl.edu>; <accredit@aaalac.org>; (b) (6) (b) (6)

Subject: Washington University in St. Louis protocol suspension report

Attached is a report of a protocol suspension at Washington University in St. Louis, Assurance #A3381-01. Please let me know if you need further information. Sincerely,

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