



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

July 24, 2020

Re: Animal Welfare Assurance  
A3472-01 [OLAW Case 5I]

Dr. David Russell  
Vice President and Dean of Basic Research  
University of Texas Southwestern Medical Center  
5323 Harry Hines Boulevard  
Dallas, TX 75390-9002

Dear Dr. Russell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 22, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Southwestern Medical Center following up on an initial January 29, 2020 notification by telephone.

According to the information provided, this Office understands that the UT Southwestern Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure of adherence to the IACUC-approved protocol. The final report states that 24 mice were administered unapproved lidocaine cream as post-operative analgesic, and received an unapproved dose of meloxicam as post-op analgesia. The findings were observed by a Senior IACUC Liaison on January 23, 2020. A discussion was held between the principal investigator (PI) and IACUC Manager on January 24, 2020. The corrective actions included the following:

- The PI and the responsible laboratory staff member were counseled by the Sr. IACUC Liaison.
- The IACUC Manager counseled the PI on January 24, 2020 and the PI confirmed that no new surgeries would be conducted until an amendment to update the analgesia information was approved.

The amendment was submitted to the IACUC and approved on February 18, 2020. It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Texas Southwestern Medical Center has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

**Tubbs, Jai (NIH/OD) [E]**

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**From:** Tubbs, Jai (NIH/OD) [E]  
**Sent:** Monday, July 20, 2020 10:06 AM  
**To:** david.russell@utsouthwestern.edu; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** Update to preliminary report for University of Southwestern Medical Center

Hello,

I am writing to request an update to the preliminary report received by telephone on 01/29/2020. This is in reference to incorrect administration of analgesia to mice. Please provide an interim or final report soon.

Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight

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.

A3472

**UT Southwestern**  
Medical Center

David W. Russell, Ph.D.  
Vice Provost and Dean of Research  
UT Southwestern Medical School  
Department of Molecular Genetics  
Eugene McDermott Distinguished Chair

July 22, 2020

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

RE: UT Southwestern Medical Center Animal Welfare Assurance Statement # D16-00296  
Grant: R01HL069229

Dear Dr. Morse,

I write to provide a final report of non-compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals* regarding an incident in which unapproved lidocaine cream was administered to 24 mice as a post-operative analgesic. An unapproved dose of meloxicam was also administered to these animals as post-operative analgesia, although the use of meloxicam was described in the protocol. These determinations were based on observations made by a Sr. IACUC Liaison on January 23, 2020 and a discussion between the PI and an IACUC Manager on January 24, 2020. This incident was first reported to Dr. Jacquelyn Tubbs via voicemail message by an IACUC Manager on January 29, 2020.

The Sr. IACUC Liaison counseled the PI and the responsible laboratory staff member on January 23, 2020. The IACUC Manager counseled the PI on January 24, 2020 and the PI confirmed that no new surgeries would be conducted until an amendment to update the analgesia information was approved. This amendment was submitted to the IACUC on January 23, 2020 and approved on February 18, 2020.

We believe the actions taken by the IACUC are appropriate for this situation.

Yours sincerely,

(b) (6)

David W. Russell, Ph.D.  
Vice Provost, Dean of Basic Research, and Institutional Official

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, July 24, 2020 7:27 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report to OLAW

Thank you for this report, (b) (6) We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Thursday, July 23, 2020 5:06 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) David  
Russell <David.Russell@UTSouthwestern.edu>  
**Subject:** Report to OLAW

To the Division of Compliance Oversight,

Attached is a final report of non-compliance. Please let me know if you have any questions regarding this report.

(b) (6)

(b) (6)

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**UT**  
**Southwestern**  
Medical Center  
The future of medicine, today.



## Initial Report of Noncompliance

By: TubbsDate: 01/29/2020Time: 6:13pmName of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: Univ Texas Southwestern Medical CenterAssurance number: D16-00296Did incident involve PHS funded activity? YFunding component: NHLBIWas funding component contacted (if necessary):           

What happened?

Jan 9th lab staff did not give correct analgesia per the approved protocol for a mouse surgery discovered by IACUC

Species involved: mousePersonnel involved: lab staffDates and times: Jan 9thAnimal deaths: NoProjected plan and schedule for correction/prevention (if known):           

IACUC still reviewing the incident, corrective action plan not developed yet, final report expected in the coming weeks

Projected submission to OLAW of final report from Institutional Official:

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Case #