



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

June 1, 2020

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

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 May 13, 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 November 15, 2019 notification by telephone.

According to the information provided, this Office understands that the University of Texas Southwestern Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states on October 16, 2019 one cage of mice was anesthetized with isoflurane for re-application of wound clips and mice received buprenorphine SR subsequently. The use of isoflurane was not approved in the protocol and the application of wound clips was performed without veterinary consultation. These findings were based on observations made by a Sr. IACUC Liaison. The incident was first reported to the IACUC manager on November 15, 2019.

The Sr. IACUC Liaison counseled the laboratory manager on October 23, 2019. The manager confirmed the cessation of unapproved anesthetics until IACUC approval could be granted. The individual responsible for performing the surgery completed hands-on retraining with staff on the proper use of wound clips on November 5, 2019. A request to add isoflurane to the protocol was submitted on December 10, 2019 to the IACUC as part of the PI's renewal submission. The renewal was approved on March 30, 2020 with the option for isoflurane anesthesia.

It is noted that the 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,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2020.06.01 12:27:11
-04'00'

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

cc: IACUC Contact

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

May 13, 2020

Brent Morse, DVM
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: 5R35CA220449

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 on October 16, 2019 in which one cage of mice was anesthetized with isoflurane for re-application of wound clips and received buprenorphine SR afterwards. The use of isoflurane was not described in the IACUC approved protocol and the wound clip application was conducted without veterinary consultation. These determinations were based on observations made by a Sr. IACUC Liaison. This incident was first reported to you via voicemail message by an IACUC Manager on November 15, 2019.

The Sr. IACUC Liaison counseled the laboratory manager on October 23, 2019. The laboratory manager confirmed that the administration of unapproved anesthetics would cease until approval could be granted. The individual responsible for performing surgery completed a hands-on retraining class with staff on the proper use of wound clips on November 5, 2019. A request to add isoflurane as an anesthetic option to the protocol was submitted to the IACUC on December 10, 2019 as part of the PI's ongoing renewal submission for that protocol. This renewal was approved on March 30, 2020 with the option for isoflurane anesthesia.

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 Research, and Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 29, 2020 7:34 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: Wednesday, May 27, 2020 6:04 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.

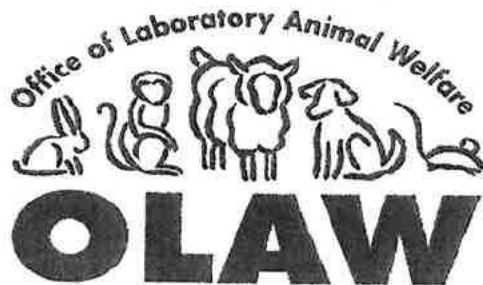
(b) (6)

(b) (6)

UT Southwestern

Medical Center

The future of medicine, today.



Initial Report of Noncompliance

By: (b) (6)

Date: 11/15/19

Time: 6:40

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: UT Texas Southwestern Med Ctr

Assurance number: A3472

Did incident involve PHS funded activity? Yes

Funding component: NCI

Was funding component contacted (if necessary): _____

What happened?

*Used isoflurane for surgery + to reapply wound clip.
Drug + clip procedure not on protocol*

Species involved: Mouse?

Personnel involved: Lab staff

Dates and times: 10/16/19

Animal deaths:

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

Counsel lab staff

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____