



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

September 3, 2021

Re: Animal Welfare Assurance
A3472-01 [OLAW Case 6E]

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 August 27, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Texas – Southwestern Medical Center. Your letter supplements the information in the preliminary telephone report to our office on July 1, 2021. According to the information supplied, OLAW understands that on June 14, 2021 a research staff member did not administer the protocol-required analgesic regimen to three cages of post-operative mice. The protocol requires the administration of both an opioid and an NSAID; however, only an NSAID was provided to these animals. This incident involved animals that were supported by funding from the PHS.

Corrective and preventive actions included the research staff member and the PI being counseled by a Sr. IACUC liaison and by an IACUC Manager. The research staff member and PI agreed to administer analgesia per the approved protocol. As of August 23, 2021, no further issues have been observed.

The prompt consideration of this matter by the University of Texas – Southwestern Medical Center was consistent with the philosophy of institutional self-regulation and self-correction. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2021.09.03 11:01:31 -04'00'

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

cc: IACUC contact

13472

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

August 27, 2021

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: R01DK109408 & 1R01DK119341-01A1

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 June 14, 2021. The IACUC determined that a research staff member did not administer the approved analgesic regimen to three cages of post-operative mice. The approved protocol describes the administration of both an opioid and an NSAID; however, only an NSAID was provided to these animals. This determination was based on observations made by clinical veterinary staff. The incident was first reported to you on June 25, 2021 via a voicemail message from an IACUC Manager.

The research staff member and PI were counseled on June 15, 2021 and June 16, 2021 by a Sr. IACUC Liaison, and on June 23, 2021 by an IACUC Manager. The research staff member and PI agreed to administer analgesia per the approved protocol. As of August 23, 2021, no further issues have been observed.

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: Wednesday, September 1, 2021 7:33 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report to OLAW

Thank you for this report. We will send a response soon.

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

From: (b) (6)
Sent: Monday, August 30, 2021 5:10 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) David Russell <David.Russell@UTSouthwestern.edu>; (b) (6)
Subject: Report to OLAW

To the Division of Compliance Oversight,

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

Thank you,

(b) (6)

UT Southwestern

Medical Center

The future of medicine, today.



Initial Report of Noncompliance

By: BCM

Date: 7/1/2021

Time: Voicemail

Name of Person reporting: _____

(b) (6)

Telephone #: _____

(b) (6)

Fax #: _____

Email: _____

Name of Institution: Univ. of Texas Southwest Med Cen. _____

Assurance number: A3472 _____

Did incident involve PHS funded activity? __yes__

Funding component: NIDDK _____

Was funding component contacted (if necessary): _____

What happened?

Mice not given proper post-operative analgesic regimen per protocol.

Species involved: ~~rat~~ *MUS*

Personnel involved: research staff

Dates and times: 6/14/2021

Animal deaths: No

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

Counseling of research staff.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY

Case # _____