



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 14, 2021

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

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 June 10, 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 March 12, 2021. According to the information supplied, OLAW understands that on March 5, 2021 a research staff member did not administer the proper analgesia regimen, post-operatively, to 12 cages of mice. The staff member did not administer the buprenorphine HCL dose required at 8- 12 hours after the dose administered at the time of surgery. This incident involved animals that were supported by funding from the PHS.

Corrective and preventive actions included the research staff member being counseled by an IACUC liaison and confirming that analgesia would be administered as approved moving forward. As of June 10, 2021, following subsequent post-approval monitoring, 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: 2021.06.14 11:56:29 -04'00'

Brent C. Morse, DVM
Director
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

June 10, 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: (b) (4)

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 March 5, 2021. The IACUC determined that a research staff member did not administer the proper analgesia regimen post-operatively to 12 cages of mice. The staff member did not administer the buprenorphine HCL dose required at 8-12 hours after the dose administered at the time of surgery. This determination was based on observations made by a Sr. IACUC Liaison. This incident was first reported to you via voicemail message by an IACUC Manager on March 12, 2021.

The research staff member was counseled by a Sr. IACUC Liaison on March 5, 2021 and confirmed that analgesia would be administered as approved moving forward. As of June 10, 2021, following subsequent post-approval monitoring, 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: Friday, June 11, 2021 7:08 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: Thursday, June 10, 2021 2:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: David Russell <David.Russell@UTSouthwestern.edu>; (b) (6)
(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: 3/12/2021

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-op analgesia.

Species involved: mice

Personnel involved: researcher

Dates and times: 3/5/2021

Animal deaths:

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

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Case #