



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 27, 2022

Re: Animal Welfare Assurance
A3472-01 [OLAW Case 61]

Dr. Joan Conaway
Vice Provost and Dean of Basic Research
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, TX 75390-9002

Dear Dr. Conaway,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 23, 2022 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 May 23, 2022. According to the information supplied, OLAW understands that on May 12, 2022, fourteen rats were administered Buprenorphine SR by a research lab member, but not Meloxicam, post-operatively, as described in the protocol. Additionally, 17 rats had been fed an unapproved special diet over the course of several months. This determination was based on observations made by clinical veterinary staff. The associated activity is PHS-funded.

Corrective and preventive actions: On May 13, 2022, the clinical veterinarian informed the lab that an amendment would be needed if the modified analgesic regimen and special diet will be used for future studies. The Sr. IACUC Liaison also met with the research staff and PI on May 19, 2022, to provide further counseling and confirm that all unapproved work had been discontinued. An amendment to add the special diet and update the analgesic regimen was approved by the IACUC on June 6, 2022.

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. Please note: data collected as a result of the administration of the unapproved feed should not be used in future grant applications, and the cost of the feed should not be charged to the grant. 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: 2022.06.27 16:00:24 -04'00'

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

cc: IACUC contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Monday, June 27, 2022 6:58 PM
To: joan.conaway@utsouthwestern.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD);
(b) (6)
Subject: OLAW Cases A3472-6H and A3472-6I
Attachments: Conaway UTSWMC 3472-6H.pdf; Conaway UTSWMC 3472-6I.pdf

Hello Dr. Conaway,

Attached please find Dr. Morse's final responses to OLAW Cases A3472-6H and A3472-6I. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

A3472-6I

UT Southwestern
Medical Center

June 23, 2022

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: R01HL151632

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 May 12, 2022. The IACUC determined a research staff member did not follow the approved analgesic regimen for 14 rats. Rats were administered Buprenorphine SR, but not Meloxicam, post-operatively, as described in the protocol. Additionally, 17 rats had been fed an unapproved special diet over the course of several months. This determination was based on observations made by clinical veterinary staff. This was first reported to you on May 23, 2022, via voicemail message from an IACUC Regulatory Monitoring Analyst.

On May 13, 2022 the clinical veterinarian informed the lab that an amendment would be needed if the modified analgesic regimen and special diet will be used for future studies. The Sr. IACUC Liaison also met with the research staff and PI on May 19, 2022, to provide further counseling and confirm that all unapproved work had been discontinued. An amendment to add the special diet and update the analgesic regimen was approved by the IACUC on June 6, 2022.

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

Yours sincerely,
(b) (6)

Joan W. Conaway, PhD
Vice Provost, Dean of Basic Research, and Institutional Official
University of Texas Southwestern Medical Center

A3472-6I



Initial Report of Noncompliance

By: BCM

Date: 5/23/2022

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: NHLBI

Was funding component contacted (if necessary):

What happened? Analgesic administered that was not in the approved protocol. Also, rats given an unapproved special diet.

Species involved: Rattus

Personnel involved: research staff

Dates and times: 5/18/22

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

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Case #