



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 6C]

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 8, 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 25, 2021. According to the information supplied, OLAW understands that on March 12, 2021 a research staff member administered an IACUC-approved special diet to six cages of mice using an unapproved feeding method. The staff member also did not monitor these animals at the frequency described in the approved protocol, and one dead mouse was found on March 10, 2021 and another on March 11, 2021. 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 the laboratory manager confirming that animals would be monitored per the approved protocol. An amendment would also be submitted to update the method of diet administration, but On March 30, 2021, it was observed that eight cages of mice were being administered the special diet using the unapproved method although the amendment had not yet been submitted. The PI was counseled and voluntarily terminated the experiment. The amendment was submitted and was subsequently approved.

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. Although it is troubling that the unapproved feeding method continued to be used, OLAW recognizes that your program dealt with the issue accordingly. 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 11:58:17 -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 8, 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: 1 R01GM134700-01

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 12, 2021. The IACUC determined that a research staff member administered a special diet described within the IACUC-approved protocol to six cages of mice using an unapproved feeding method. The IACUC determined that this staff member also did not monitor these animals at the frequency described in the approved protocol, and animal facility veterinary staff found one dead mouse on March 10, 2021 and another on March 11, 2021. 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 March 25, 2021.

The responsible staff member was counseled by a Sr. IACUC Liaison on March 12, 2021. On March 22, 2021, the laboratory manager confirmed that animals would be monitored per the approved protocol and an amendment would be submitted to update the method of diet administration.

On March 30, 2021, a Sr. IACUC Liaison observed eight cages of mice being administered the approved special diet using the unapproved method, since the amendment to update the method of diet administration had not yet been submitted. The PI was counseled by an IACUC Manager on April 1, 2021 and voluntarily terminated the experiment immediately. An amendment was submitted on April 12, 2021 to update the description of the diet administration and this amendment was approved by the IACUC on May 19, 2021.

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, June 9, 2021 7:45 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: Tuesday, June 8, 2021 3:36 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: 3/25/2021

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 properly monitored or properly administering special diet.

Species involved: mice
Personnel involved: researcher
Dates and times: 3/12/2021
Animal deaths:

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

Counseling of research staff. Possible protocol amendment.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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Case #