



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

January 24, 2022

Re: Animal Welfare Assurance
A3345-01 [OLAW Case 1H]

Dr. Jennifer Sharpe Potter
Interim Vice President for Research
University of Texas Health Science Center - San Antonio
7703 Floyd Curl Drive, MC 7764
San Antonio, TX 78229-3900

Dear Dr. Potter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 11, 2022 letter reporting an adverse event at the University of Texas Health Science Center at San Antonio. According to the information provided, OLAW understands that three mice died, and an additional mouse was found in moribund condition, following the conduct of lingual nerve denervation and cancer cell inoculation procedures. All procedures were performed as described in the IACUC-approved protocol, including monitoring and body weight assessments until 30 days post-inoculation. In accordance with the approved protocol, the provision of softened food was not warranted since animals did not display any weight loss or welfare issues. The animal activity in question was PHS funded.

The corrective actions consisted of modifying the monitoring plan to include daily body weight and welfare assessments for 30 days post cell inoculation and amending the protocol to include provision of softened diet beginning at 30 days post cell inoculation, regardless of weight or ability to eat solid food.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.
Gopee -S
Date: 2022.01.24 11:08:42 -05'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Director, Division of Policy and Education
Office of Laboratory Animal Welfare
National Institutes of Health

CC: IACUC contact



OLAW Assurance #A3345-01

Date: January 11, 2022

To:



From: Institutional Animal Care and Use Committee (IACUC)

DocuSigned by:

(b) (6)

Cc: Jennifer Potter, PhD, MPH, Professor, Vice President for Research, Institutional Official

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(b) (6)

Brent Morse, Division of Compliance Oversight, OLAW

Subject: Full Committee Review of Prompt Report

Dear Principal Investigator,

A Prompt Report for the above listed protocol was reviewed by the Institutional Animal Care and Use Committee (IACUC) during the December 15, 2021 IACUC meeting.

Summary of the event (including any required interventions and animal disposition): Department of Laboratory Animal Resources (DLAR) has reported that three mice were found dead and one in a moribund condition for this study examining the effect of lingual nerve denervation on tumor growth and body weight. A DLAR veterinarian overseeing these animals did not observe softened food being provided in the cages of these animals which may have contributed to their death. The PI indicated that only approved procedures were performed on the animals and all monitoring and weight measurements were being performed. The approved protocol does indicate that softened food will be provided as needed based on weight loss. The PI reported that mice involved in this event had not shown any signs of diminished welfare or weight loss during the most recent monitoring and were performing as expected until day 30 post cell inoculation.

Actions taken to prevent recurrence: The PI temporarily suspended these experiments to identify both the cause of welfare decline and best course of action. The PI provided a corrective action plan to enhance the monitoring plan to include daily body weight and welfare assessments every day after 30 days of cancer cells inoculation. Additionally, softened food will be provided starting at 30 days post inoculations of cancer cell regardless of weight or ability to eat solid food.

Determination/IACUC Directed Actions: The Committee determined that the event was an unexpected adverse event and did not meet the criteria for noncompliance. The Committee determined that the research continues to satisfy the requirements for IACUC approval. The corrective action plan was acceptable as written. The investigator will continue to monitor the study and report to the IACUC according to applicable policies and procedures.

The Committee directed the PI to address the following non-substantive items:

- The PI must submit the amendment associated with the corrective action plan by January 31, 2022.

The corrective actions must be addressed promptly. Please reply to this letter within **14 days** from the date on this letter and send your **point-by-point** response to the Committee to IACP@uthscsa.edu.

Reporting: The UTHSCSA IACUC will report these finding to the following entities: IO, AVPRA, AAALAC, OLAW

Please retain this document in your IACUC correspondence file

Institutional Animal Care Program | Mail Code 7822 | 7703 Floyd Curl Drive | San Antonio, Texas 78229-3900
210.567.8260 | Fax 210.567.8242 | <http://research.uthscsa.edu/iacuc>

Name	Species	Source of Funding	Sponsor Tracking Number
THE ROLE OF PERIPHERAL BRAIN-DERIVED NEUROTROPHIC FACTOR (BDNF) SIGNALING IN ORAL CANCER PAIN	Mice	NIH-NATIONAL INSTITUTES OF HEALTH	R01 DE027223
LIGHT and Lymphotoxin targeting in the treatment of chronic orofacial pain conditions	Mice	HHS-NIH-NIDCR	R01 DE029187

Your point of contact on this issue is (b) (6)

Sincerely,

(b) (6)

(Please retain this document in your IACUC correspondence file)

Institutional Animal Care Program	Mail Code 7822	7703 Floyd Curl Drive	San Antonio, Texas 78229-3900
210.567.8260	Fax 210.567.8242	http://research.uthscsa.edu/iacuc	

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 12, 2022 11:26 AM
To: IACP
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UTHSCSA - #A3345-01 - Report of Unexpected Adverse Event & Report of Noncompliance

Thank you for these reports. We will send responses soon.

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

From: (b) (6) On Behalf Of IACP
Sent: Wednesday, January 12, 2022 11:16 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] UTHSCSA - #A3345-01 - Report of Unexpected Adverse Event & Report of Noncompliance
Importance: High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Morse,

The UT Health San Antonio, in accordance with PHS/OLAW reporting requirements, submits the attached reports of two incidents for an NIH-funded study.

If further information is required, please contact (b) (6)

Thank you.

Sincerely

(b) (6)