



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 30, 2021

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

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 September 29, 2021 letter in response to OLAW's September 23, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Health Science Center at San Antonio. According to the information provided, OLAW understands that animals were transferred into Optimice cages on July 8, 2021. During the interim period while awaiting transfer to Optimice caging, increased daily monitoring of headplate affixed animals was conducted by the principal investigator and husbandry staff. No additional incidents during the interim period were noted.

OLAW appreciates the prompt consideration of this matter by the University of Texas Health Science Center at San Antonio which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact



MEMORANDUM

TO: Nicole Lukovsky-Akhsanov, D.V.M., M.P.H., DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: [REDACTED] (b) (6)

CC: Jennifer Sharpe Potter, Ph.D. M.P.H.; Interim Vice President for Research,
Institutional Official
Kristine Vogel, Ph.D., Associate Professor, IACUC Chair
Sander Hacker, V.M.D.; Attending Veterinarian

DATE: September 29, 2021

RE: OLAW Case A3345-1D

Thank you for your inquiry into the reported unexpected adverse event (OLAW Case A3345-1D) in which the following additional information was requested:

- *In the interim while caging systems are being changed, please provide information on steps being taken to reduce potential pain and distress such as increased monitoring when headplates are affixed to animals.*

UTHSCSA Response:

The PI, in collaboration with the Attending Veterinarian, successfully transferred associated mice to Optimice cages on July 8, 2021. During the interim period, while awaiting the transfer to Optimice cages, increased, daily monitoring of the headplate animals both by the PI and/or husbandry staff was performed. Monitoring personnel detected no additional incidents during this interim period. If you have any additional questions, please contact me directly.



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September 23, 2021

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

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 August 2, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Health Science Center at San Antonio. According to the information provided, OLAW understands that in accordance with the approval IACUC protocol, a metal headplate was surgically attached to a mouse skull to perform in-vivo microscopy studies. During routine health checks, a staff veterinarian observed one mouse's headplate was stuck in the cage's water bottle spout and the headplate was partially separated from the skull. Clinical care was provided to alleviate any potential pain and distress however the headplate could not be repaired or reattached and the animal was humanely euthanized. This study was supported by PHS funding.

As a corrective measure, the principal investigator (PI) explained that this kind of incident is rare however veterinary staff was consulted for recommendations to prevent recurrence. The PI informed that IACUC they will continue to work with veterinary staff to change to Optimice cage systems which maintain alternative water systems to eliminate potential recurrence of the similar incident in the future. An amendment will be submitted to include the potential for metal headplate damage as an adverse event.

OLAW appreciates the prompt consideration of this matter by the University of Texas Health Science Center at San Antonio which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests the following information:

- In the interim while caging systems are being changed, please provide information on steps being taken to reduce potential pain and distress such as increased monitoring when headplates are affixed to animals.

We look forward to your responses to the to the additional information request by **October 15, 2021** to **Nicole.Lukovsky@NIH.gov** We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact



OLAW Assurance #A3345-01

Date: August 02, 2021

To:



From: Institutional Animal Care and Use Committee (IACUC)

Cc: Jennifer Potter, PhD, MPH, Professor, Vice President for Research, Institutional Official
 Brent Morse, Division of Compliance Oversight, OLAW
 Kathryn Bayne, AAALAC, International

(b) (6)

Digitally signed by
 Jennifer Sharpe Potter
 Date: 2021.08.02
 14:44:49 -05'00'

Subject: Full Committee Review of Prompt Report (Dated 06/30/2021)



Dear Principal Investigator,

A Prompt Report for the above listed protocol was reviewed by the Institutional Animal Care and Use Committee (IACUC) during the June 30, 2021 IACUC meeting.

Summary of the event (including any required interventions and animal disposition): In accordance with the approved IACUC procedures, a metal headplate was surgically attached to a mouse skull to perform in vivo microscopy studies. During routine health checks a DLAR veterinarian observed that one mouse's headplate was stuck in the cage's water bottle spout and the headplate was partially separated from the skull. The veterinarian provided the necessary clinical care to alleviate any potential pain and distress of the mouse. The veterinarian consulted with the PI and it was determined that the headplate could not be repaired and reattachment would not be possible and therefore the animal was humanely euthanized.

Actions taken to prevent recurrence: The PI explained that this kind of incident is extremely rare however they consulted with DLAR veterinarians for recommendations for preventing recurrence. The PI has informed the IACUC that they will work with DLAR to change to Optimice cage systems, which maintain alternative water systems which may eliminate headplate interaction. The PI has indicated that they will submit an amendment to include the possibility of the metal headplate damage, as an expected adverse event.

Determination/IACUC Directed Actions: The Committee determined that the event was an unexpected adverse event due to the approved IACUC protocol procedures 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 implement the following additional corrective actions:

- The PI must submit an amendment to the protocol to include the possibility of the metal headplate damage, as an expected adverse event.

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.

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>

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

Name	Species	Source of Funding	Sponsor Tracking Number
THE ROLE OF ASTROGLIA IN BRAIN STATE DEPENDENT NEURAL ACTIVITY	Mice	NIH	R01 MH113780
ETHANOL AND BRAIN STATE- DEPENDENT NEURAL SIGNALING	Mice	NIH	R01 AA025128

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

Sincerely,

(b) (6)

(Please retain this document in your IACUC correspondence file)

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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, August 4, 2021 7:24 AM
To: IACP
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UTHSCSA - #A3345-01 - Report of Noncompliance

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

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

From: (b) (6) On Behalf Of IACP
Sent: Tuesday, August 3, 2021 9:25 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: UTHSCSA - #A3345-01 - Report of Noncompliance
Importance: High

Division of Compliance Oversight
Office of Laboratory Animal Welfare
c/o Dr. Brent Morse, Division of Compliance Oversight, OLAW
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-915-9466
E-mail: olawdco@mail.nih.gov

Dear Dr. Morse,

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

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

Thank you.

Sincerely

(b) (6)