



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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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 8, 2022

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

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 May 18, 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 Health Science Center at San Antonio (UT Health, San Antonio). According to the information provided, OLAW understands that a principal investigator (PI) used nonpharmaceutical grade (NPG) ketamine/xylazine solution for approved surgical procedures and did not keep appropriate logbook records for ketamine use. No negative health or welfare outcomes were noted in these animals, and they responded to anesthesia normally. The PI was unaware that the ketamine/xylazine solution was NPG. The mice and rats involved in this incident were supported by NIH funding.

Corrective and preventive measures included the following: 1) The PI has temporarily stopped the use of unapproved, NPG compounds and will submit an amendment to request approval for the use of the NPG ketamine/xylazine compounded solution for terminal procedures. 2) The PI will purchase pharmaceutical grade ketamine and xylazine for use in approved surgical procedures. 3) The laboratory members will check the approved protocol before ordering drugs to see whether there is an exception, or the drug must be pharmaceutical grade. 4) The PI will maintain an appropriate logbook for ketamine solution. 5) The IACUC determined that the PI must also develop and implement an SOP to ensure that current and future laboratory personnel have reviewed and understand the approved protocol and the existing IACUC policy regarding NPG substances. Further, the SOP should ensure that laboratory members have received training from the PI on the importance of adhering to the approved protocol.

OLAW appreciates the consideration of this matter by UT Health, San Antonio which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. However, in future reports please include the approximate number of animals involved.

We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M. Engel -S  
Date: 2022.06.08 13:46:33 -04'00'

Robyn M. Engel, DVM  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare

cc: IACUC contact

A3345-1I



UT Health  
San Antonio

OLAW Assurance #A3345-01

Date: May 18, 2022

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

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 May 11, 2022 IACUC meeting.

**Summary of the event (including any required interventions and animal disposition):** During the semiannual inspection of [REDACTED] (Laboratory Room# [REDACTED]), it was found that the PI is using a non-pharmaceutical grade (NPG) Ketamine/Xylazine solution (purchased from Sigma-Millipore, part#K113) in animals for approved surgical procedures. Additionally, the PI was not keeping appropriate logbook records for ketamine use. Though the use of ketamine/xylazine in animals is approved, the use of NPG-grade anesthetic mixtures has not been approved by the IACUC. No negative health or welfare outcomes were noted in these animals and all animals responded to this anesthesia normally. The PI has informed the IACUC that they were unaware that this ketamine/Xylazine solution is not pharmaceutical grade.

**Actions taken to prevent recurrence:** The PI has temporarily stopped the use of unapproved, nonpharmaceutical grade agents. The PI has informed the IACUC that they will submit an amendment to their protocol requesting approval for the use of non-pharmaceutical grade Ketamine/Xylazine pre-compounded solution for terminal approved procedures. The PI has indicated that they will purchase pharmaceutical grade ketamine and Xylazine for use in approved surgical procedures. The PI has informed the IACUC that he will advise all laboratory members to check the approved animal use protocol whenever they will purchase a drug to see if the drug must be a pharmaceutical grade or if there is an exception. The PI has also informed IACUC that they will maintain an appropriate logbook for ketamine solution and will continue to maintain them in the lock box at the recommended temperature.

**Determination/IACUC Directed Actions:** The Committee determined that the event met the criteria of noncompliance. The noncompliance was determined to be neither serious nor continuing. 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 develop and implement an SOP to ensure that current and future personnel have:
  - Reviewed and understand:
    - The approved IACUC protocol
    - The Nonpharmaceutical Grade Chemical or Other Substances IACUC Policy.
  - Received training from the PI on the importance for adhering to the approved IACUC protocol.

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>

The corrective actions must be addressed promptly. Please reply 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, Department Chair, OSP, OLAW, AAALAC.

Name	Species	Source of Funding	Sponsor Tracking Number
FUNCTIONAL PERIPHERAL AND CENTRAL VAGAL NEURAL CIRCUITS OF INTEROCEPTION INHIBITING PAIN	Mice, Rats	NIH	
(b) (4)			

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

Please let me know if you have any question.

Sincerely,

**Prajjal K.  
Singha**

Digitally signed by  
Prajjal K. Singha  
Date: 2022.05.18  
11:57:24 -05'00'

Prajjal K. Singha, Ph.D., MB(ASCP)<sup>CM</sup>  
Research Compliance Coordinator-Senior,  
Office of the Institutional Animal Care Program (OIACP)

(Please retain this document in your IACUC correspondence file)

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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 20, 2022 7:49 AM  
**To:** IACP  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: UTHSCSA - #A3345-01 - Report of Noncompliance

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

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

**From:** Singha, Prajjal <singhap@uthscsa.edu> **On Behalf Of** IACP  
**Sent:** Wednesday, May 18, 2022 4:49 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] 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](mailto: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)

(b) (6)

Thank you.

Sincerely  
Prajjal K. Singha, Ph.D., MB(ASCP)<sup>CM</sup>  
Research Compliance Coordinator-Senior  
Office of the Institutional Animal Care Program (IACP)  
Research Administration Bldg., (b) (4)  
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