



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 1, 2021

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

Dr. Jennifer Potter
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 an August 20, 2021 memo, bearing your signature, documenting the IACUC's review and actions regarding a report of noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at the University of Texas Health Science Center – San Antonio. According to the information provided, OLAW understands that a PI performed an unapproved pilot study using 18 mice. Nine of 18 animals died as the result of tumor development and the remaining mice were euthanized at the pilot study endpoint of 20 days. The animals were supported using PHS funds.

Corrective and preventive actions included the PI submitting an amendment to incorporate the results of the pilot study into the IACUC protocol. The PI has provided assurance that unapproved pilot studies will not be performed in the future and they will await approval from the IACUC for any modifications to the IACUC protocol. The PI will regularly review the IACUC protocol with protocol personnel and ensure all individuals have access to it.

The Committee directed the PI to implement the following additional corrective actions:

- The PI must provide documented assurance, to include signatures, that all study personnel have read and understand the IACUC protocol and have received training from the PI on the importance of strictly adhering to only the approved activities described within.

OLAW appreciates the consideration of this matter by the University of Texas Health Science Center – 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, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. Please note that although data from the unapproved pilot study belongs to the University, data from unapproved activities should not be used in PHS grant applications and should not be submitted for publication without alerting the journal. 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

Date: 2021.09.01 16:50:17 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC Contact



OLAW Assurance #A3345-01

Date: August 20, 2021

To:



From: Institutional Animal Care and Use Committee (IACUC)

Cc: Jennifer Potter, PhD, MPH, Professor, Vice President for Research, Institutional Official (b) (6)

(b) (6)

Digitally signed by Jennifer
Sharpe Potter
Date: 2021.08.20 15:58:09 -05'00'Christopher G Green, CPA, Senior Dir, Sponsored Programs, Office of Sponsored Programs
Brent Morse, Division of Compliance Oversight, OLAW

Subject: Full Committee Review of Prompt Report (Dated 07/01/2021)

Dear Principal Investigator,

A Prompt Report for the above listed protocol was reviewed by the Institutional Animal Care and Use Committee (IACUC) during the August 11, 2021 IACUC meeting.

Summary of the event (including any required interventions and animal disposition): The PI performed an unapproved pilot study using 18 mice to titrate the amount of cells to be injected to elicit tumor development for an orthotopic tongue cancer study. Three different cell volumes among two new cell lines were included in the pilot. Nine of 18 animals died as the result of tumor development and the remaining mice were euthanized at the pilot study endpoint of 20 days.

Actions taken to prevent recurrence: The PI has submitted and received approval for an amendment to incorporate the results of the pilot study into the IACUC protocol. The PI has provided their assurance that unapproved pilot studies will not be performed in the future and they will await approval from the IACUC for any modifications to the IACUC protocol. The PI will regularly review the IACUC protocol with protocol personnel and ensure all individuals have access to it via ORCA.

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 provide documented assurance, to include signatures, of the following:
 - All study personnel have read and understand the IACUC protocol and have received training from the PI on the importance of strictly adhering to only the approved activities described within.

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, AVPR, Department Chair, OSP, OLAW

Name	Species	Source of Funding	Sponsor Tracking Number
THE ROLE OF PERIPHERAL BRAIN-DERIVED NEUROTROPHIC FACTOR (BDNF) SIGNALING IN ORAL CANCER PAIN	Mice	NIH	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: Monday, August 23, 2021 7:00 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: Friday, August 20, 2021 5:31 PM
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) at IACP@uthscsa.edu or (b) (6)

Thank you.

Sincerely

(b) (6)