



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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 1F]

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 used expired Fatal-Plus to euthanize 25 mice. The use of Fatal-Plus was not in the approved protocol. No adverse welfare issues were noted. It was stated that the activity was PHS supported.

Corrective and preventive actions included the PI stopping the use of expired Fatal plus solution in animals and ordering a new bottle. An amendment, to include the use of Fatal Plus solution in animals, has been approved by the IACUC. The PI has provided training to all protocol personnel to check the expiration date of Fatal-Plus solution before use in animals and notify the PI immediately of any expired drug so that it can be stored and disposed of properly, and a new drug ordered. The PI will also regularly review all IACUC protocols with protocol personnel to ensure compliance. The Committee directed the PI to implement the following additional corrective actions:

- The PI must designate a storage space specific for expired agents, to be separated from nonexpired agents, while awaiting their disposal.

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

Sincerely,

Brent C. Morse -S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C. Morse

-S

Date: 2021.09.01 16:53:07 -04'00'

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 16:05:11
-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 06/28/2021)

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 administered an unapproved and expired euthanasia agent, FATAL-PLUS Solution. The solution was administered to 25 mice as an overdose to euthanize mice for performance of approved transcardial perfusion procedure. The PI did not observe any adverse welfare issues outside of the expected outcome for euthanasia procedures.

Actions taken to prevent recurrence: The PI has ceased the use of expired Fatal plus solution in animals and ordered a new bottle. An amendment to include the use of Fatal Plus solution in animals has now been approved by the IACUC. The PI has provided training to all protocol personnel to check the expiration date of Fatal-Plus solution before use in animals and notify the PI immediately of any expired drug so that it can be stored and disposed of properly, and a new drug ordered. The PI will also regularly review all IACUC protocols with protocol personnel to ensure compliance.

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 designate a storage space specific for expired agents, to be separated from nonexpired agents, while awaiting their disposal.

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
OPPOSING ROLES FOR MICROGLIA IN THE YOUNG AND AGED NEUROGENIC NICHE	Mice	NIH	R01 NS102448

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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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 23, 2021 7:01 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 5:33 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) (b) (6)
(b) (6) at IACP@uthscsa.edu or (b) (6)

Thank you.

Sincerely

(b) (6)