



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) 402-7065

December 12, 2019

Re: Animal Welfare Assurance
#A4107-01 (OLAW Case 1Y)

Dr. Daniel T. Jaffe
Vice President for Research
University of Texas at Austin
P.O. Box 7996
Austin, TX 78713


Dear Dr. Jaffe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 10, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Texas (UT) at Austin. Your letter supplements the information provided in a preliminary email report made on October 30, 2019. According to the information provided, OLAW understands that during an IACUC semi-annual facility evaluation, committee members found a bottle of expired carprofen that was being used for survival surgeries. The bottle was disposed at the time of inspection and this was noted to be a repeat deficiency for this laboratory. The study is supported by PHS funding.

As a corrective measure, the IACUC voted to place the investigators on the UT veterinary monitoring list which a form of post-approval monitoring (PAM). PAM representatives visited the laboratory to recheck the drug supply and will continue to perform visits until the IACUC determines the visits may cease to ensure expired drugs are not being used in the laboratory. Additionally, the investigators implemented a colored sticker system to track drug expiration and system use was confirmed during PAM visits.

OLAW appreciates the prompt consideration of this matter by The University of Texas at Austin, which is consistent with the philosophy of institutional self-regulation. 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 find no cause for further action by this office.

Sincerely,


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

cc: IACUC contact



THE UNIVERSITY OF TEXAS AT AUSTIN
Office of the Vice President for Research

P.O. Box 7996 • FAC 426, G1400 • Austin, TX 78713-7996 • 512-471-2877 • FAX 512-471-2827

December 10, 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKI, 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: Report of Non-Compliance with PHS Policy on Humane Care and Use
of Laboratory Animals

To Whom It May Concern:

The University of Texas at Austin (UT), Animal Welfare Assurance #A4107-01, submits this report in compliance with section IV.F.3 of the PHS Policy on Humane Care and Use of Laboratory Animals and with the published guidance document NOT-OD-05-034 "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals." This letter is to report non-compliance that had the potential to jeopardize animal health or welfare. The initial report was made on October 30, 2019.

During the IACUC's recent semiannual facility evaluations, committee members discovered an expired bottle of carprofen that was being used for survival surgeries past the expiration date. The bottle was disposed of at the time of inspection. As this is a repeat deficiency for this laboratory, the IACUC voted to place the investigators involved on the UT veterinary monitoring list, which is a form of post-approval monitoring (PAM).

As part of the plan for correction for this deficiency and in order to prevent reoccurrence of expired drugs being used in live animals, PAM representatives visited the laboratory and rechecked the laboratory's drug supply. The investigators have also implemented a color-sticker system to track drug expiration dates. The PAM representatives have confirmed that this requirement has been implemented. PAM visits will continue until the IACUC determines that visits may cease in order to ensure expired drugs are not being used in this laboratory.

The project involved in this report is funded by the following NIH projects:
5R21NS102964-02, entitled "*Chronic Multimodal Characterization of Peri-Infarct Depolarizations Post Stroke in Rodent*"; 1R01NS109361-01A1, entitled, "*Longitudinal Multimodal Mapping to Decipher the Neurovascular Impact of Microinfarcts*"; and

Director, Division of Compliance Oversight
December 10, 2019
Re: PHS Assurance Number A4107-01
Page 2

5K25HL140153-02, entitled, "Nanoelectronic Enabled Chronic Quantification of Neurovascular Coupling." The grant officers have been copied on this notification.

Sincerely,

(b) (6)

Daniel T. Jaffe
Vice President for Research
University of Texas at Austin

DTJ:cim

cc: Kathryn Bayne, Global Director, AAALAC
S. John Mihic, Chair, Institutional Animal Care and Use Committee (b) (6)
James Koenig, Program Official, NIH
Li-Shin Huang, Program Official, NIH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 11, 2019 10:42 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance- University of Texas at Austin

Thank you. We will respond soon.

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

From: IACUC <IACUC@austin.utexas.edu>
Sent: Wednesday, December 11, 2019 10:36 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <IACUC@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>; (b) (6)
(b) (6) Koenig, Jim (NIH/NINDS) [E]
<jim.koenig@nih.gov>; Huang, Li-Shin (NIH/NHLBI) [E] <li-shin.huang@nih.gov>; Jaffe, Dan <dtj@austin.utexas.edu>
Subject: Report of noncompliance- University of Texas at Austin

Good morning,

Oh behalf of Dr. Daniel Jaffe, Vice President for Research at the University of Texas at Austin, please find attached the final report involving an adverse event with NIH grant awards 5R21NS102964-02, 1R01NS109361-01A1, and 5K25HL140153-02. The initial report was made October 30, 2019. Please let me know if you have any questions.

Thank you,

(b) (6)

A4107-1Y

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 30, 2019 11:00 AM
To: IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Jaffe, Dan; (b) (6) Mihic, S J; (b) (6)
Subject: RE: Initial report of noncompliance

Thank you for providing this preliminary report (b) (6) We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: IACUC [mailto:IACUC@austin.utexas.edu]
Sent: Wednesday, October 30, 2019 10:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Jaffe, Dan <dtj@austin.utexas.edu>; (b) (6) Mihic, S J
<mihic@austin.utexas.edu>; (b) (6)
IACUC <IACUC@austin.utexas.edu>
Subject: Initial report of noncompliance

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

To Whom It May Concern,

On behalf of Dr. Daniel Jaffe, VP of Research, please accept this initial report of non-compliance for NIH project numbers 5R21NS102964-02, 1R01NS109361-01A1, and 5K25HL140153-02, under Assurance number A4107-01.

During the IACUC's recent semiannual facility evaluations, committee members discovered a bottle of Carprofen that was past expiration. The laboratory representative reported that the expired Carprofen was used for survival surgeries. The bottle was disposed of at the time of the inspection. The IACUC formed a subcommittee to investigate this noncompliance further outside of semiannual facility evaluations. The use of expired Carprofen in animal procedures is a repeat deficiency in this lab, and for that reason, the IACUC voted to place the investigators involved on the UT Austin veterinary monitoring list, which is a form of post-approval monitoring.

As per NOT-OD-05-034, conditions that jeopardize the health or well-being of animals are reportable.

The IACUC will continue to review the matter. After finishing the review, a final report of its conclusions and actions will be submitted to the Office of Laboratory Animal Welfare. In the meantime, please let me know if you have any questions.

Sincerely,

(b) (6)