

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

February 20, 2020

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

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 February 11, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas at Austin, following up on an initial report on January 23, 2020. According to the information provided, OLAW understands that two rats failed to receive protocol mandated analgesia following surgery. The animals were showing abnormal neurologic symptoms.

The immediate action taken upon discovery consisted of contacting the veterinarian and euthanizing the rats. The investigators and staff were counseled on following the protocol, undertook retraining on post-operative care and pain relief, and enlisted an experienced surgeon as a mentor. The laboratory staff will train on cadavers and move on to live animals under direct veterinary oversight and direction.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



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

February 11, 2020

Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health RKL 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 in which the investigator failed to adhere to the IACUC-approved protocol. The initial report was made on January 23, 2020.

During daily animal checks, animal care staff discovered two rats that were showing neurologic symptoms the day after undergoing surgery. After consulting with a clinical veterinarian and the principal investigator, the animals were promptly euthanized. These animals had not been administered analgesia as described in the approved animal use protocol.

An IACUC subcommittee, consisting of the chair and veterinary and IACUC staff met with the investigators involved and developed plans for correction. The importance of following protocol was emphasized to the investigators. The investigators also completed an online training about post-procedure care for rodents, which includes modules about how to prevent, detect clinical signs of, and alleviate pain and distress. An experienced surgeon from another laboratory was identified to work with and provide additional training to the individual performing surgeries. The surgeons are performing the procedure on cadavers prior to using live animals. Once training on cadavers is complete, the surgeons will use live animals under veterinary oversight. Veterinary staff will help ensure proper surgical technique, analgesia use, and post-operative recovery.

Director, Division of Compliance Oversight February 11, 2020 Re: PHS Assurance Number A4107-01 Page 2

The protocol this report pertains to is funded by NIH project number 1R21MH119253-01, entitled "Dopamine Timing-Dependent Plasticity in Reward Learning". The grant officer has been copied on this notification.

Sincerely,

(b) (6)

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

DTJ:cim

cc:

S. John Mihic, Chair, Institutional Animal Care and Use Committee

(b) (6

Glen Otto, Attending Veterinarian, Institutional Animal Care and Use Committee

Laurie Nadler, Program Official, NIH

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, February 13, 2020 10:53 AM

To:

IACUC

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: University of Texas at Austin final report of noncompliance

Thank you for this report,

(b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

From: IACUC <IACUC@austin.utexas.edu>
Sent: Thursday, February 13, 2020 10:09 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Nadler, Laurie (NIH/NIMH) [E] < Inadler@mail.nih.gov>; Jaffe, Dan < dtj@austin.utexas.edu>; Mihic, S J

<mihic@austin.utexas.edu>;

(b) (6)

IACUC <IACUC@austin.utexas.edu>

Subject: University of Texas at Austin final report of noncompliance

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 noncompliance with NIH grant award 1R21MH119253-01. The initial report was made on January 23, 2020. Please let me know if you have any questions.

Thank you,

(b) (6)

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, January 23, 2020 12:01 PM

To:

IACUC; OLAW Division of Compliance Oversight (NIH/OD)

Cc:

Jaffe, Dan; Mihic, S J;

Subject:

RE: Initial report of noncompliance - Assurance A4107-01

Thank you for providing this initial report. We will open a compliance 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

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From: IACUC [mailto:IACUC@austin.utexas.edu]
Sent: Thursday, January 23, 2020 11:57 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Jaffe, Dan <dtj@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>;

(b) (6)

(b) (6) IACUC < IACUC@austin.utexas.edu>

Subject: Initial report of noncompliance - Assurance A4107-01

To Whom It May Concern,

On behalf of Dr. Daniel Jaffe, Vice President of Research at the University of Texas at Austin, please accept this initial report of non-compliance for NIH project number 1R21MH119253-01, under Assurance A4107-01.

During daily animal checks, animal care staff discovered two rats that were showing neurologic symptoms the day after undergoing surgery. After promptly consulting with a clinical veterinarian and the principal investigator, the animals were euthanized. Veterinary staff were notified that these animals had not been administered analgesia as described in the approved animal use protocol. The IACUC began an investigation into this matter. The principal investigator and laboratory staff are currently working with the IACUC to determine an adequate training plan for surgeons in this laboratory prior to more surgeries being performed.

As per NOT-OD-05-034, failure to adhere to IACUC-approved protocols is 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,

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