



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 1W)

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 multiple bottles of ketamine that were past expiration. The committee members reviewed controlled substance logs maintained by the investigator and discovered that expired ketamine was used on two occasions. The IACUC formed a subcommittee to further investigate this occurrence outside of semiannual facility evaluations. The study is supported by PHS funding.

As a corrective measure, IACUC representatives revisited the laboratory and confirmed that the expired drugs have been disposed. The investigator is now required to submit monthly records of drug inventory to the IACUC. Additionally, the investigators implemented a colored sticker system to track drug expiration and an IACUC representative confirmed requirements have been implemented.

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  
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 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 multiple bottles of ketamine that were past expiration. The committee members reviewed controlled substance logs maintained by the investigator and discovered that the expired ketamine was used in two occasions. The IACUC formed a subcommittee to further investigate this occurrence outside of semiannual facility evaluations.

As part of the plan for correction for this deficiency and in order to prevent reoccurrence of expired drugs being used in live animals, IACUC representatives revisited the laboratory and confirmed that the expired drugs have been disposed of. In addition, the investigator is required to submit monthly records of drug inventory to the IACUC. The investigator has also implemented a color-sticker system to track drug expiration dates. An IACUC representative has confirmed that these requirements have been implemented.

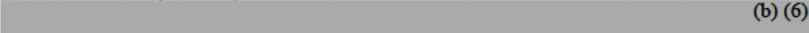
The project involved in this report is funded by NIH, project number 1R21MH119253-01 entitled "*Dopamine Timing-Dependent Plasticity in Reward Learning*". The grant officer has been copied on this notification.

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

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)  
Laurie Nadler, Program Official, NIH

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, December 11, 2019 11:22 AM  
**To:** IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of noncompliance- University of Texas at Austin

Thanks. We'll respond soon.  
Axel Wolff

**From:** IACUC <IACUC@austin.utexas.edu>  
**Sent:** Wednesday, December 11, 2019 10:41 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** IACUC <IACUC@austin.utexas.edu>; Jaffe, Dan <dtj@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>;  
(b) (6) Nadler, Laurie (NIH/NIMH) [E]  
<lnadler@mail.nih.gov>  
**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 noncompliance with NIH grant award 1R21MH119253-01. The initial report was made October 30, 2019. Please let me know if you have any questions.

Thank you,

(b) (6)

A4107-1W

**Morse, Brent (NIH/OD) [E]**

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**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

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**From:** IACUC [mailto:IACUC@austin.utexas.edu]  
**Sent:** Wednesday, October 30, 2019 10:12 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 number 1R21MH119253-01, under Assurance number A4107-01.

During the IACUC's recent semiannual facility evaluations, committee members discovered multiple bottles of ketamine that were past expiration. The committee members reviewed controlled substance logs maintained by the investigator and discovered that the expired ketamine was used in two occasions. The IACUC formed a subcommittee to further investigate this occurrence outside of semiannual facility evaluations. IACUC representatives will revisit this investigator's laboratory in order to verify that expired pharmaceuticals are not being used in animals.

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)