



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 1V)

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 responding to OLAW concerns regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The University of Texas at Austin.

According to the information provided, OLAW understands that this event was fatal for two animals and the remaining 14 animals recovered. Laboratory staff monitor animals exposed to ethanol vapor at least twice daily including checking flow rates visually to ensure chambers are functioning properly. UT will be contacting collaborators at the Scripps Research Institute to inquire about active monitoring however the IACUC does not feel that such a system should be required as this adverse event was not due to an equipment malfunction but human error. Additionally, a checklist has been implemented and laboratory personnel have been trained on using the checklist. Personnel are aware of the human error that attributed to the adverse event, proper chamber function and a mounted cable management system was installed as corrective measures to prevent reoccurrence.

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. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

 (b) (6)
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

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
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 an Adverse Event: Animal Welfare Assurance # A4107-01
(OLAW Case 1V)

Dear Dr. Lukovsky-Akhsanov:

Thank you for your response dated November 20, 2019 regarding an adverse event at the University of Texas at Austin (UT) involving unexpected mortality in animals while in ethanol vapor chambers. Below contains updates in response to those requested by OLAW.

Sixteen animals were impacted by this incident. This event was fatal for two animals and the remaining fourteen recovered. UT appreciates OLAW's suggestion to consider an active monitoring system. There is currently no such system on the vapor chambers. Laboratory staff monitor animals exposed to ethanol vapor at least twice daily. In addition, flow rates are visually checked twice daily to ensure that chambers are functioning properly. IACUC representatives inspected the newly implemented and mounted cable management system and found this to be acceptable. The IACUC discussed the possibility of requiring an active monitoring system at the December 9, 2019 full committee meeting. UT will contact collaborators at The Scripps Research Institute to inquire about active monitoring systems currently available. However, the IACUC does not feel that such system should be required as this adverse event was not due to an equipment malfunction. It was the result of a personnel error and because of the corrective measures that have been implemented, the lab is no longer at risk of this error reoccurring.

A checklist has been implemented to ensure the animals are checked regularly for intoxication and chamber flow rates are checked regularly for proper function. Laboratory personnel have been trained on using this newly implemented checklist. Personnel are aware of the human error that is attributed to this adverse event, proper chamber function, and that a mounted cable management system was installed as a corrective measure to prevent reoccurrence.

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

UT will report any further issues of non-compliance as mandated by NOT-OD-05-034 "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" and Assurance A4107-01. Please let us know if you require further updates regarding our ongoing oversight implemented in response to this event.

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)
Qi-Ying Liu, Program Official, NIH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 11, 2019 10:27 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of Texas at Austin Adverse Event- OLAW Case 1V

Thank you for this report, (b) (6) 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 10:19 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>
Subject: FW: University of Texas at Austin Adverse Event- OLAW Case 1V

My apologies, I used the incorrect email address. Please see below. Thank you!

From: IACUC <IACUC@austin.utexas.edu>
Sent: Wednesday, December 11, 2019 9:16 AM
To: olaw@od.nih.gov
Cc: Jaffe, Dan <dtj@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>; (b) (6)
(b) (6) liuqi@mail.nih.gov; IACUC <IACUC@austin.utexas.edu>
Subject: University of Texas at Austin Adverse Event- OLAW Case 1V

Good morning,

Oh behalf of Dr. Daniel Jaffe at the University of Texas at Austin (Animal Welfare Assurance # A4107-01), please accept this response to Dr. Lukovsky-Akhsanov's letter regarding OLAW Case 1V. Please let us know if you have any questions.

Thank you,

(b) (6)



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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

November 20, 2019

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

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 November 7, 2019 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. Your letter supplements the information provided in a preliminary emailed report sent on September 18, 2019.

According to the information provided, OLAW understands that on September 7, 2019, rats were placed into ethanol vapor chambers overnight and discovered to be unresponsive the following morning at which time personnel opened the chambers to allow for ventilation. Rats were noted to be extremely intoxicated and two animals died. Veterinary technicians and the on-call veterinarian provided assistance to the surviving rats which were treated and recovered. As part of the IACUC investigation, it was found that laboratory personnel accidentally disconnected power cables from a power strip, which due to the loss of power caused the chambers to malfunction and were unable to dilute the ethanol vapor creating high ethanol concentrations.

During IACUC inspection of the lab, as a corrective measure it was noted that the power cables were secured with a cable management system attached to the power strip. Additionally, the power strip was mounted to the wall to decrease the likelihood it could be disconnected again.

While 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, we request further information regarding the event reported. Based on the information provided, we have additional questions as follows:

- How many total animals were impacted by the malfunctioning chamber?
- Is there an active monitoring system including alarm settings in the laboratory to notify personnel of concerns when animals are housed in the chambers?
- Is a checklist being implemented to ensure appropriate steps have been taken and checked each time animals are in the chambers?
- Has any re-training been performed to ensure all personnel are aware of proper chamber function?

OLAW expects that in addition to correcting the concern at hand, institutions take further steps to reduce and prevent the likelihood of future occurrences. Please provide details regarding how your institution is working to prevent similar incidents in the future from recurring no later than **December 9th, 2019**. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

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

cc: IACUC contact



OFFICE OF RESEARCH SUPPORT
THE UNIVERSITY OF TEXAS AT AUSTIN

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November 7, 2019

Axel Wolff, M.S., D.V.M.
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 an Adverse Event with PHS Policy on Humane Care and Use
of Laboratory Animals

Dear Dr. Wolff:

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 an adverse event affecting animal health or welfare. The initial report was made September 18, 2019.

On September 7, 2019, rats were placed into ethanol vapor chambers for overnight exposure. The following morning, lab personnel discovered that they were unresponsive. The personnel opened the chambers to ventilate the ethanol vapor. The rats were extremely intoxicated and two animals died. With assistance from veterinary technicians and the on-call clinical veterinarian, the surviving rats were treated and recovered.

In the process of this investigation, the IACUC identified that the incident was a result of laboratory personnel accidentally disconnecting power cables from a power strip. Due to the loss of power, the chambers were unable to function properly to dilute the ethanol vapor, resulting in high ethanol concentrations within. IACUC members, facility management, and Environmental Health and Safety personnel visited the laboratory to inspect the current setup for the ethanol chambers and found them to be adequate. The power cables have been secured with a cable management system that is attached to the power strip. In addition, the power strip was mounted to the wall, further decreasing the chance that it could accidentally disconnect again.

The project involved in this report is funded by NIH, project number 5R01AA026075-03 entitled "*CRF Neurons Of The Extended Amygdala And Alcohol Drinking*". The grant officer has been copied on this notification.

Axel Wolff, Director, Division of Compliance Oversight
November 7, 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:aem

cc: Kathryn Bayne, Global Director, AAALAC
S. John Mihic, Chair, Institutional Animal Care and Use Committee
(b) (6)
Qi-Ying Liu, Program Official, NIH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 15, 2019 6:52 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report of an adverse event

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, November 14, 2019 12:10 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Liu, Qi-Ying (NIH/NIAAA) [E] <liuqiy@mail.nih.gov>; Mihic, S J <mihic@austin.utexas.edu>; (b) (6)
(b) (6) Jaffe, Dan <dtj@austin.utexas.edu>
Subject: Final report of an adverse event

To whom it may concern,

Of 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 award 5R01AA026075-03. The initial report was made September 18, 2019. Please let me know if you have any questions.

Thank you,

(b) (6)

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, September 19, 2019 7:05 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Initial report of an adverse event

Thank you for this preliminary report (b) (6) We will open a case file and wait for your final report.

Regards,
 Joan

*Joan Ward
 Program Specialist
 Office of Laboratory Animal Welfare
 National Institutes of Health
 6700B Rockledge Dr., Suite 2500
 Bethesda, MD 20892
 301-496-7163
wardjoa@od.nih.gov*

From: IACUC <IACUC@austin.utexas.edu>
Sent: Wednesday, September 18, 2019 5:53 PM
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 an adverse event

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

Dear Dr. Wolff,

On behalf of Dr. Daniel Jaffe, Vice President for Research at the University of Texas at Austin, please accept this initial report of an adverse event for NIH award number 5R01AA026075-03, under Assurance number A4107-01.

On September 7, 2019, rats were placed into ethanol vapor chambers for overnight exposure. The following morning, lab personnel discovered that they were unresponsive. The personnel opened the chambers to ventilate the ethanol vapor. The rats were extremely intoxicated and two animals died. With assistance from veterinary technicians and the on-call clinical veterinarian, the surviving rats were treated and recovered.

This incident appears at this time to be a result of lab personnel accidentally disconnecting power cables from a power strip. Due to the loss of power, the chambers were unable to function properly to dilute the ethanol vapor, resulting in high ethanol concentrations within.

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

Thank you.

(b) (6)

