



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 9, 2018

Re: Animal Welfare Assurance
#A3340-01 (OLAW Case Y)

Dr. Roberto Osegueda
Vice President for Research
The University of Texas at El Paso
500 W. University Avenue
Administration Building, (b) (4)
El Paso, TX 79968

Dear Dr. Osegueda,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 17, 2016 letter reporting two adverse events at The University of Texas at El Paso. According to the information provided, OLAW understands that on January 26, 2018, static discharge caused the interface of a brand new pump to malfunction which resulted in the pump dispensing all of the contents into the animal. The animal subsequently displayed signs of moderate pain, dehydration, anorexia and conjunctivitis and was administered supportive therapy. The Principal Investigator contacted the manufacturer and implemented several preventative measures including the addition of a new code in the program and procuring static-reducing wipes for the chambers and a humidifier for the room. A subsequent malfunction of the system occurred on February 8, 2018 which affected three of the nine active chambers and resulted in the complete dispensing of the contents into three rats. One rat died and one of the remaining two animals that was administered supportive therapy was euthanized.

The corrective actions included the PI immediately halting all future experiments until the issue was resolved, contacting the manufacturer for additional assistance, switching out some of the parts, introducing a 24 hour humidifier, using anti-static wipes in the procedure room and incorporating additional codes to the program to reduce the probability of errors. The PI resumed research activity five days following the implementation of the above mentioned preventive measures by first using only saline in the syringe to ensure proper functioning of the equipment.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

THE UNIVERSITY OF TEXAS AT EL PASO



April 5, 2018

Institutional Animal
Care and Use Office

Brent C. Morse, DVM, DACLAM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Re: Assurance #D16-00221[A3340-01]

Dear Dr. Morse:

The University of Texas at El Paso (UTEP), in accordance with Assurance #D16-00221 [A3340-01] and PHS Policy IV.F.3., provides this report concerning animal welfare issues on protocol A201708-1: The effects of diet on the reinforcing effects of drugs. The IACUC office communicated the incident to OLAW with a preliminary report and requested a case be opened on February 1, 2018 on behalf of the IO.

On January 26, 2018 during wellness checks, LARC personnel identified an experimental animal that looked unwell. The animal exhibited signs of moderate pain, dehydration, anorexia, and conjunctivitis. The Attending Veterinarian (AV) was contacted and the animal was provided supportive treatment.

The AV then notified the IACUC Chair, IACUC Office and the IO. The IACUC Chair appointed a sub-committee to investigate the incident.

The sub-committee met with the PI to discuss the incident. The PI stated the pumps are brand new, and the pump itself was not the issue. The PI contacted the company manufacturer and as per their conversation, the issue was static discharge. This caused the interface (not the pump) to malfunction, which resulted in dispensing all of the content in the syringe, regulated by the pump. At the time of the interview with the PI, she had already taken several measures to prevent this static related malfunction from re-occurring. This included the addition of new code in the program which the equipment uses to determine how long the pump should be active, as well as the purchase of static-reducing wipes for the chambers, and a humidifier for the room to prevent very dry air (which promotes static).

Although preventative measures had been placed, the PI experienced another malfunction on February 08, 2018. An update from the PI stated this was not an electrostatic shock as before. This malfunction only occurred to 3 of 9 active chambers, unlike the previous incident. Further, the computer program gave an error message, which did not happen previously.

During this incident, 3 pumps dispensed all fluid, and as a result, one rat was lost. Two other animals were affected and received preventative care. One animal recovered and the other was euthanized. The PI immediately suspended the experiments until the issue was resolved.

500 W. University Ave.
El Paso, Texas
79968
(915) 747-8355
FAX: (915) 747-6063

The PI contacted the manufacturer again for guidance. The PI then switched out some parts, introduced a 24 hour humidifier and started using anti-static wipes in the procedure room to prevent electrostatic shock related problems. The PI also added additional codes to the program to reduce error probability. The PI resumed experimental activity about 5 days after implementing the additional preventative measure but only used saline to ensure equipment was functioning properly. The PI felt confident with the newly implemented preventative measure and has resumed experimental procedures.

The subcommittee felt the PI took appropriate action and implemented necessary preventative measures and had no additional recommendations. This was proposed to the IACUC committee at a fully convened IACUC meeting on March 24, 2016 and approved.

I concur with the committee that no additional recommendations are necessary. The University of Texas at El Paso is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me at (b) (6) or via e-mail at osegueda@utep.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Roberto A. Osegueda, PhD
Vice President for Research
Institutional Official
The University of Texas at El Paso

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 06, 2018 7:34 AM
To: Fester, Athena
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Thank you for this report. We will send a response soon.
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Fester, Athena [mailto:afester@utep.edu]
Sent: Thursday, April 05, 2018 3:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Osegueda, Roberto A. <osegueda@utep.edu>; (b) (6)
(b) (6)
(b) (6)
Subject: RE: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Good Afternoon Dr. Morse,

Attached is the final report for the incident initially reported to OLAW on February 1, 2018.

If you have any questions or concerns, please feel free to contact our IACUC office.

Sincerely,

Athena

Athena Fester, MS
Director of Regulatory Assurances
University of Texas at El Paso
Office of Research & Sponsored Projects
Kelly Hall, (b) (4)
(b) (6)

afester@utep.edu

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Thursday, February 01, 2018 11:20 AM
To: Inst Animal Care & Use Committee <iacuc@utep.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Osegueda, Roberto A. <osegueda@utep.edu>; (b) (6)
(b) (6) Fester, Athena <afester@utep.edu>; (b) (6)

(b) (6)@utep.edu>

Subject: RE: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Thank you for sending this preliminary report Ms. Fester. We will open a case file and await further information.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting 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: Inst Animal Care & Use Committee [mailto:iacuc@utep.edu]

Sent: Thursday, February 01, 2018 1:16 PM

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

Cc: Osegueda, Roberto A. <osegueda@utep.edu>;

(b) (6)

(b) (6) Fester, Athena <afester@utep.edu>;

(b) (6)

(b) (6)@utep.edu>

Subject: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Dear OLAW Division of Compliance Oversight,

On behalf of the Institutional Official, this email is to inform you of an incident involving an experimental animal found that looked unhealthy during morning wellness checks.

Briefly, the animal exhibited signs of moderate pain, dehydration, anorexia, and conjunctivitis. The animal was provided supportive treatment. The cage was tagged for continued monitoring and an investigation is underway.

We request a case be opened for the incident and a more detailed report will be sent with the corrective measures at a later time.

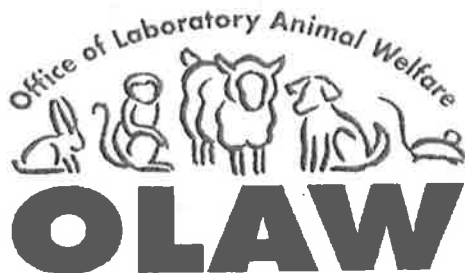
Please contact the IACUC office if you have any questions.

Sincerely,

Athena

Athena Fester, MS
Director of Regulatory Assurances
University of Texas at El Paso
Office of Research & Sponsored Projects
Kelly Hall, (b) (4)
(b) (6)

afester@utep.edu



Initial Report of Noncompliance

By: Neera Gopee

Date: 2-8-18

Time: 3:53 PM

Name of Person reporting: Athena Foster

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: University of Texas at El Paso

Assurance number: A3340-01

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Incident reported via email on 2-1-18 was found to be caused by malfunctioned equipment. On 2-8-18 a second animal died due to the equipment malfunctioning again.

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, February 01, 2018 1:20 PM
To: Inst Animal Care & Use Committee; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Osegueda, Roberto A.; (b) (6) Fester, Athena; (b) (6)
Subject: RE: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Thank you for sending this preliminary report Ms. Fester. We will open a case file and await further information.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Acting 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: Inst Animal Care & Use Committee [mailto:iacuc@utep.edu]
Sent: Thursday, February 01, 2018 1:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Osegueda, Roberto A. <osegueda@utep.edu>; (b) (6) Fester, Athena <afester@utep.edu>; (b) (6)@utep.edu
Subject: Assurance # D16-00221 [A3340-01]; Preliminary Incident Report

Dear OLAW Division of Compliance Oversight,

On behalf of the Institutional Official, this email is to inform you of an incident involving an experimental animal found that looked unhealthy during morning wellness checks.

Briefly, the animal exhibited signs of moderate pain, dehydration, anorexia, and conjunctivitis. The animal was provided supportive treatment. The cage was tagged for continued monitoring and an investigation is underway.

We request a case be opened for the incident and a more detailed report will be sent with the corrective measures at a later time.

Please contact the IACUC office if you have any questions.

Sincerely,

Athena

Athena Fester, MS
Director of Regulatory Assurances
University of Texas at El Paso
Office of Research & Sponsored Projects
Kelly Hall, (b) (4)
(b) (6)
afester@utep.edu