



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 2, 2019

Re: Animal Welfare Assurance
A3783-01 [OLAW Case F]

Dr. Larry Howell
Associate Academic Vice President
for Research & Graduate Studies
Brigham Young University
A376 ASB Campus Drive
Provo, Utah 84602

Dear Dr. Howell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brigham Young University. According to the information provided, OLAW understands that three rats, on an approved protocol, died after being injected with alcohol. Following necropsy it was determined that all three rats had peritonitis, most likely a result of poor injection technique. Also, the cage cards had the wrong protocol number and emergency contact information.

The corrective actions consisted of removing the student responsible from the protocol, improving the training regarding drug preparation and injection, updating cage cards, retraining staff on cage card information, and improving communication between the research staff and veterinary and animal care staff.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Division of Compliance Oversight

cc: IACUC Chair

LARRY L. HOWELL
Associate Academic Vice President for Research
& Graduate Studies



November 18, 2019

VIA EMAIL

olawdco@mail.nih.gov

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

Re: Final Noncompliance Report from BYU (Assurance #A3783-01)

Dear Dr. Wolff,

Brigham Young University, in accordance with Assurance D16-00461 (A3783-01) and PHS Policy IV.F.3, provides this report of an adverse event regarding conditions that jeopardize the health or well-being of animals. Specifically, the death of three rats resulting from attempts to inject the rats with Alcohol. The IACUC determined that the animals in question were associated with an animal study protocol entitled "Nicotine and Alcohol Co-Dependence," research directly supported by NIH Grant R01 DA035958. A preliminary report for this incident was first given to Dr. Axel Wolff on September 11, 2019 via a telephone call by (b) (6)

On April 29th, 2019 the animal care staff noted that three distinct cages in Kimball Tower each had a dead rat. The cage mates were still alive, and there was sufficient food and water for the animals. At the time, it was suspected that some treatment of the animals had gone awry, possibly an injection of alcohol. The veterinarian noted that it was difficult to determine the cause of death, and also to know who to notify, because the wrong protocol was written on the cage card and the wrong emergency contact name and phone number were listed. (b) (4)

A necropsy on the three rats was conducted on May 10, 2019. The overall diagnosis was severe, acute peritonitis of all the rats that were examined. All the rats were found to be in good body condition and weighed between 400 and 550 grams at

necropsy. After a phone discussion with the diagnostic veterinarian, barring the use of a dirty needle, we have concluded that it is most likely that the injection method itself may have caused damage by deep punctures or lacerations to the intestinal tract that led to peritonitis. Mucosal intestinal damage was noted along with focal areas of infection of coccobacilli and degenerative neutrophils. A discussion with (b) (6) (b) (6) the post-doc responsible for this particular study, also supported the possibility of poor injection technique by one of the students.

The IACUC discussed the incident and requested corrective actions from the PI.

To address the situation, the PI took the following actions:

1. Submitted correspondence to the IACUC on May 29, 2019 and August 22, 2019 in response to requests for information. The PI acknowledged the incident and confirmed the cause as being improper injection technique by one undergraduate student researcher. PI asserted that the student had been properly trained.
2. Described corrective measures that would be implemented to prevent future incidents of this nature. The measures included:
 - a. Removing the student from the project
 - b. Reviewing procedures and improving the training process related to drug preparation and injection
 - c. Updating protocol numbers and contact information as necessary and retraining on this procedure
3. Committed to improving animal care by keeping open lines of communication with appropriate animal care staff and the Veterinarian.

The IACUC met on September 3, 2019 and reviewed and accepted the corrective actions as submitted by the PI. The IACUC determined that this was an isolated incident and not a programmatic failure.

Brigham Young University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW. Should you have any questions regarding this report, please contact our IACUC administrator.

Sincerely,

(b) (6)

Larry Howell
Associate Academic Vice President
Brigham Young University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 20, 2019 8:07 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report for preliminary report given on Sept. 11, 2019

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Monday, November 18, 2019 6:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final report for preliminary report given on Sept. 11, 2019

Dr. Wolff,

Please see the attached Noncompliance Report for the preliminary report given to you on September 11, 2019.

(b) (6)