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

April 24, 2020

Re: Animal Welfare Assurance
A4706-01 [OLAW Case D]

Dr. Gary R. Burleson
President and CEO
Burleson Research Technologies, Inc.
120 First Flight Lane
Morrisville, NC 27560

Dear Dr. Burleson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 20, 2020 letter reporting an instance of an adverse event with the PHS Policy on Humane Care and Use of Laboratory Animals at Burleson Research Technologies following up on an initial March 2, 2020 notification by telephone.

According to the information provided, this Office understands that the Burleson Research Technologies Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: death of a mouse after a cage slid off a rack and hit the floor. The final report states on February 28, 2020, mice were moved in their IVC cages from the vivarium to the procedure room for sheep blood cell immunization using a mobile rack. The procedure was completed, and the mice were being moved back to their home rack in the vivarium when a caster dislodged from one corner of the mobile cart. This caused the rack to lean significantly and 7 out of 18 cages slid off the rack onto the floor. The technician moving the mice held the rack up to provide time for lab members to join and support the rack and gather the mice. In total, 27 mice from the affected cages were recovered and placed in fresh IVC cages with their original cage mates. A single mouse was found dead in one of the cages that hit the floor; cause of death was not evident from necropsy. The remaining mice were examined shortly after the incident and no evidence or trauma or health abnormalities were observed per the report. These animals were quarantined and kept on study and continued to appear healthy until scheduled euthanasia 4 days after the incident.

The mobile rack was examined after the incident. It was discovered that another caster was found to be improperly seated in the rack, along with the initial failed caster. It was concluded that the failures were related to improper replacement of the casters ~5yr. ago. The rack will not be used until it is repaired or replaced. It is noted that other mobile racks were examined and found to be free of defects and all mobile racks will be placed on a monthly schedule for examination of casters.

The IACUC was notified of the incident on March 2, 2020 and it was discussed at the convened meeting on April 15, 2020. The committee agreed this was an equipment-related accident and not the result of inadequate personnel training or attention.

It is noted that these animals were involved in PHS supported activities. Based on its assessment of this explanation, OLAW understands that Burleson Research Technologies has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by Jacquelyn T. Tubbs -S
Date: 2020.04.28 11:01:51 -04'00'

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

BRT
Burleson Research Technologies

April 20, 2020

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

Dear Dr. Morse:

Burleson Research Technologies, Inc., in accordance with Assurance # D16-00898 and PHS Policy IV.F.3., provides this report of an adverse event regarding a mouse death after a cage slid off a rack and hit the floor. This incident was reported to Dr. Jai Tubbs by telephone on 2 Mar 2020, by Richard Fish, DVM, PhD, DACLAM, BRT Attending Veterinarian and IACUC Chair. The mice were on study and covered under an IACUC-approved protocol (BIC # PACMAPMIX, Approved 4 Oct 2019).

On 28 Feb 2020, mice were moved in their IVC cages from the vivarium to the procedure room for sheep red blood cell immunization using a mobile rack. Immunization was completed and the mice were being moved back to their home rack in the vivarium when a caster dislodged from one corner of the mobile cart. This caused the rack to lean significantly and 7 out of 18 cages slid off the rack onto the floor. The technician moving the mice held the rack up to provide time for her lab mates to join and support the rack and gather the mice. Three technicians gathered the mice in about 5 minutes from the time of the incident. Twenty-seven mice from the affected cages were recovered and placed in fresh IVC cages with their original cage mates, but a single mouse was found dead in one of the cages that hit the floor; cause of death was not evident from necropsy. The Study Director was notified immediately, and he and the Attending Veterinarian examined the remaining 27 mice shortly after the incident to determine health status; animals appeared normal, were alert, responsive and active, and had no evident trauma. It was decided to quarantine the mice, but keep them on study, and animals continued to appear healthy in daily observations until scheduled euthanasia 4 days after the incident.

The mobile rack used to transport mouse cages was examined after the incident. In addition to the one caster that failed, another was also found to be improperly seated in the rack and could be easily removed. We concluded that the failures were related to improper replacement of the casters approx. 5 years ago; the affected rack will not be used until repaired or replaced. Other mobile racks were examined and found to be sound, and all mobile racks will be placed on a monthly schedule for caster examination.

BRT
Burleson Research Technologies

The BRT IACUC was notified by email of the incident on 2 Mar 2020, and discussed the incident at a convened meeting on 15 April 2020. Members were in agreement that this was an unforeseeable, equipment-related accident, and not the result of inadequate personnel training or attention.

Grant/contract number: HHSN273201400017C

Impact on PHS-supported activities: This incident was discussed with the NTP COR who was in agreement with the decision of the BRT Study Director and Attending Veterinarian to maintain the animals on study under quarantine as they appeared healthy. This was a decision in the best interest of the animals and prevented unnecessary repeating of the study. The animals stayed healthy until the scheduled necropsy. Data obtained from these animals were consistent with historical results indicating that the incident did not impact the outcome of the intended use of the animals. Therefore, there is no impact of this incident.

BRT 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 Richard Fish, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Gary R. Burleson, PhD
President, CEO, and Institutional Official
Burleson Research Technologies, Inc.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 24, 2020 10:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Report

Thank you for this report. We will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, April 24, 2020 10:34 AM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Adverse Event Report

FYI. I'll put the hard copy in your mailbox.

From: (b) (6)
Sent: Friday, April 24, 2020 10:14 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Adverse Event Report

BRT

(b) (6)

A4706 - D

Office of Laboratory Animal Welfare
OLAW

Initial Report of Noncompliance

By: TJdos

Date: 03/02/2020 Time: 2:44p

Name of Person reporting: RickFish
Telephone #: [redacted] (b) (6)
Fax #:
Email: rfish@brt-labs.com

Name of Institution: BurleSon
Assurance number: D16-00898

Did incident involve PHS funded activity? Y
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
3 mouse cages on rack being moved to another room when caster came off, 7 mouse cages hit the floor, 1 mouse died instantly

Species involved: MUS
Personnel involved: Animal Care Staff
Dates and times: Feb 28th
Animal deaths: 1

Projected plan and schedule for correction/prevention (if known): _____
90d.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____