



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

January 24, 2020

Re: Animal Welfare Assurance  
A3413-01 [OLAW Case 2K]

Michael R. Blackburn, Ph.D.  
Executive Vice President and  
Chief Academic Officer  
University of Texas Health Science Center-Houston  
7000 Fannin St., UCT-1732  
Houston, TX 77030

Dear Dr. Blackburn,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 22, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas Health Science Center at Houston, following up on an initial telephone report on December 23, 2019. According to the information provided, OLAW understands that three cages of mouse pups were not weaned by laboratory staff on the day stipulated in the protocol, which led to overcrowded cages. No adverse incidents occurred with the mice.

The corrective action consisted of notifying the laboratory staff and having the husbandry staff wean the mice. The laboratory staff was counseled on weaning mice on the due date and to promptly respond to notifications of overcrowded cages. Husbandry staff is to be notified in advance of a pending weaning so they can separate the animals if laboratory staff is unavailable.

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  
Office of Laboratory Animal Welfare

cc: IACUC Contact



**Office of the Executive Vice President  
and Chief Academic Officer**

Michael R. Blackburn, Ph.D.  
*Executive Vice President, Chief Academic Officer*

January 22, 2020

Brent Morse, D.V.M., DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
Rockledge One, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

**Re: Assurance A3413-01**

Dear Dr. Morse,

The Animal Welfare Committee (AWC), the Institutional Animal Care and Use Committee for the University of Texas Health Science Center at Houston (UTHealth) provides this report of failure to adhere to the AWC approved protocol. In accordance with Assurance A3413-01 and PHS Policy IV.F.3.a., a preliminary report was made by the (b) (6) to you on December 20, 2019.

Per the approved protocol, mice are to be weaned at day 21 or 28 as a 28-day weaning age exception was approved by the AWC. On October 22, 2019, laboratory personnel did not wean a single cage whereby pups were due to be weaned at 28 days of age. Similarly, on October 24, 2019, laboratory personnel did not wean two cages of pups whereby pups were due to be weaned at 21 days of age resulting in overcrowded cages. Center for Laboratory Animal Medicine and Care (CLAMC) husbandry staff notified the laboratory staff of the three overcrowded cages. Because laboratory personnel failed to wean the cages within the deadline provided by CLAMC, the three cages were weaned by CLAMC husbandry staff. Per the Mouse Cage Density and Overcrowding AWC Policy, repeated failure to respond to CLAMC requests for separation, defined as failure to separate three overcrowded cages within 30 days, triggers a protocol deviation. No clinical consequences resulted from the overcrowded cages.

Although this was an isolated incident, laboratory personnel were reminded to wean the litters on the due dates and to respond to any overcrowded cage notifications provided by CLAMC promptly. Additionally, for situations for which laboratory personnel cannot be present, personnel were encouraged to contact CLAMC in advance of the weaning due dates to schedule for CLAMC husbandry personnel to wean the litters in order to prevent overcrowding.

The animals involved in this incident were supported by NIH funding (5R01DK109574-04). No significant costs associated with this event were identified. Funds will be returned if associated costs are identified.

The AWC Protocol Deviation Subcommittee has investigated the incident, evaluated the corrective action plan, and feels that the incident has been successfully resolved.

Please do not hesitate to contact me if you have any questions or comments.

Sincerely,

(b) (6)

Michael R. Blackburn, Ph.D.  
Executive Vice President and Chief Academic Officer

MRB/tsl

cc: Dr. Christophe Ribelayga, IACUC Chair

(b) (6)

AWC Office

(b) (6)

(b) (6)

7000 Fannin St., UCT-1732  
Houston, TX 77030

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, January 24, 2020 7:19 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Final Reports - Assurance A3413-01

Thank you for these reports, (b) (6) We will send replies soon.

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

**From:** (b) (6)  
**Sent:** Wednesday, January 22, 2020 6:48 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Blackburn, Michael R <Michael.R.Blackburn@uth.tmc.edu>; Ribelayga, Christophe P <Christophe.P.Ribelayga@uth.tmc.edu>; (b) (6) Animal Welfare Committee, GM <awc@uth.tmc.edu>  
**Subject:** OLAW Final Reports - Assurance A3413-01  
**Importance:** High

*Sent on behalf of Michael R. Blackburn, Ph.D.,  
EVP & Chief Academic Officer/Institutional Official, UTHealth—*

Good Evening, Dr. Morse –

Please find attached four (4) PDFs concerning the following:

- RCR-19-023;
- RCR-19-025;
- RCR-19-026; and
- RCR-19-027.

Please advise if you should have any issues with receiving the attachments.

Thanks and regards,  
(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: *sgm*Date: *12/23/19*Time: *Voicemail*Name of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: *U. Texas - Health*Assurance number: *A3413*Did incident involve PHS funded activity? *Yes*

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened? *Failure to wean 3 cages of mice per protocol + institutional policy.*Species involved: *Mouse*Personnel involved: *Researcher*

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

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

Projected submission to OLAW of final report from Institutional Official: \_\_\_\_\_

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Case # \_\_\_\_\_