



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

February 4, 2020

Re: Animal Welfare Assurance  
A3413-01 [OLAW Case 20]

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 31, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at UTHealth following up on an initial January 28, 2020 notification by telephone.

According to the information provided, this Office understands that UTHealth Animal Welfare Committee (AWC) determined that instances of noncompliance occurred with respect to: unapproved personnel manipulating animals. The final report states a qualified and trained individual performed protocol approved behavioral tests on 16 rats between January 3 and January 21, 2020. The Principal Investigator has several approved protocols a majority of which, include behavioral testing that was performed by a senior lab member who recently left the lab. The individual responsible for this incident assumed the duties of behavioral testing, but due to an oversight the person was never added as personnel on the protocol for which this incident occurred. The report states no clinical consequences to the animals resulted from this incident. An amendment to add the individual was submitted on January 23 and approved by the AWC on January 27, 2020. It is noted this incident was supported by NIH funding, and no significant costs associated with this event were identified.

Based on its assessment of this explanation, OLAW understands that UTHealth 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,

(b) (6)

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

cc: IACUC Contact



**The University of Texas**  
Health Science Center at Houston

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

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

January 31, 2020

Jacquelyn Tubbs, D.V.M.  
Veterinary Medical Officer, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

**Re: Assurance A3413-01**

Dear Dr. Tubbs,

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 unapproved personnel manipulating animals. 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 January 28, 2020.

On January 21, 2020, the AWC received a report of unapproved personnel manipulating animals. Specifically, the individual responsible for this incident performed approved behavioral tests on sixteen rats between January 3 and January 21, 2020. Although the individual was appropriately qualified and trained, the individual was not listed as approved personnel on the protocol for which this incident occurred. The Principle Investigator has several approved protocols a majority of which have approved behavioral testing that was performed by a senior laboratory member who recently left the laboratory. Consequently, the individual responsible for this incident took over the responsibilities for performing the behavioral testing as this individual is listed as approved personnel on the other protocols. Because of an oversight the individual was never added as personnel on the protocol for which this incident occurred. No clinical consequences to the animals resulted from this incident.

The individual was not allowed to manipulate any animals until the personnel amendment request was submitted and approved. A protocol amendment to add the individual was submitted on January 23 and approved by the AWC on January 27, 2020.

The animals involved in this incident were supported by NIH funding (5R01NS090935-05). 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

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, February 04, 2020 11:44 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Blackburn, Michael R; Ribelayga, Christophe P; (b) (6) Animal Welfare Committee, GM  
**Subject:** RE: OLAW Final Report - Assurance A3413-01

Thank you for this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** (b) (6)  
**Sent:** Monday, February 03, 2020 2:35 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 Report - Assurance A3413-01  
**Importance:** High

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

Good Afternoon, Dr. Tubbs,

Please find attached one (1) PDF concerning the above-referenced.  
Please advise if you have any issues with receiving the attachment.

Thanks and regards,

(b) (6)

(b) (6)

(b) (6)



## Initial Report of Noncompliance

By: Tubbs

Date: 01/28/2020

Time: 10:45A  
(b) (6)

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: UT Health

Assurance number: A 3413-01

Did incident involve PHS funded activity? 4

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

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

What happened?

Unapproved personnel working w/ SD rats doing behavior testing

Species involved: SD rats

Personnel involved: lab personnel

Dates and times: Jan 3-21<sup>st</sup> 2020

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

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

Amend. Submitted, it was approved yesterday to add personnel

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

OFFICE USE ONLY

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