



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

October 17, 2019

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

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 September 30<sup>th</sup>, 2019 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. Your letter supplements the information provided in a preliminary telephone report on August 8<sup>th</sup>, 2019. According to the information provided, OLAW understands that on May 29<sup>th</sup>, 2019, thirty-six female mice were aerosol infected with *Mycobacterium tuberculosis* with a projected endpoint for June 25<sup>th</sup>, as approved on the protocol. On June 21<sup>st</sup>, three mice that had exhibited clinical signs prior were found dead. Half of the remaining mice also exhibited similar clinical signs and were euthanized on June 21<sup>st</sup> while the rest of the animals received supportive care and euthanized at the expected endpoint. The animals on this study were supported by NIH funding.

Corrective actions included sample analysis that revealed heavier than anticipated infection which was hypothesized to be due to a mutation during organism expansion prior to infection in mice. To prevent future occurrences, the expanded strain that resulted in clinical concern as related above will not be used and future experiments will use expansion of frozen stock with known experimental viability and expected growth patterns.

OLAW appreciates the prompt consideration of this matter by The University of Texas, Health Science Center at Houston which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
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*

September 30, 2019

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 approved experimental manipulations resulting in clinical consequences and deaths to 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 August 8, 2019.

On June 26, 2019, the AWC received a report of approved experimental manipulations resulting in clinical consequences and deaths to animals. Thirty-six female mice were aerosol infected with *Mycobacterium tuberculosis* on May 29, 2019, as approved on the protocol with a projected endpoint for June 25, 4 weeks post-infection. On June 21, three infected mice (which had been showing clinical consequences) were found dead. Half of the remaining mice also showing similar clinical consequences were euthanized on June 21 and tissues were harvested for analyses. The remaining mice were provided additional supportive care with increased monitoring and were euthanized at the approved experimental end time point. The analyzed samples revealed a heavier infection outcome than expected, and the Principal Investigator hypothesized that a mutation had arisen during expansion of the organism before the infection of the mice. To prevent the possibility of similar outcomes in the future, the specific expanded strain that resulted in the clinical consequences will no longer be used. Future experiments will utilize expansion of frozen stocks of strains with known experimental viability with normal and expected grown patterns that are maintained by the laboratory.

The animals involved in this incident were supported by NIH funding (1R35HL144805-01). 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.  
Institutional Official  
Executive Vice President and Chief Academic Officer

MRB/tsl

cc: Dr. Christophe Ribelayga, IACUC Chair

(b) (6)

AWC Office

713.500.3544 phone 713.500.3059 fax  
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:** Monday, September 30, 2019 3:52 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD); OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Blackburn, Michael R; Ribelayga, Christophe P; (b) (6) Animal Welfare Committee, GM  
**Subject:** RE: Assurance A3413-01

Thank you for providing 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, September 30, 2019 3:50 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:** Assurance A3413-01  
**Importance:** High

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

Dear Dr. Morse,

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)





Initial Report of Noncompliance

By: *[Signature]*

Date: 8/8/19

Time: Voicemail (b) (6)

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Univ. of Texas HSC - Houston  
Assurance number: A3413

Did incident involve PHS funded activity? Yes

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

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

What happened? 36 mice received M. tuberculosis. 3 died. Determined that a mutation of the inoculum resulted in ↑ virulence.

Species involved: mouse

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 # \_\_\_\_\_