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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

March 2, 2022

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

Re: Animal Welfare Assurance A3413-01 [OLAW Case 3F]

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 February 7, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Texas Health Science Center at Houston. Your letter supplemented the information contained in an initial telephone report to this office on January 31, 2022. According to the information provided, OLAW understands that on January 5, 2022, it was reported that two cages of mice underwent an intracranial injection of tumor cells. Although the surgical procedure is approved on the protocol, the individual who performed the procedures was not approved on the protocol as a surgeon. The individual responsible for this incident was appropriately qualified and trained and certified to perform the procedure. No clinical consequences resulted from this incident. The post-surgical procedural monitoring, care, and analgesic administration were properly documented on the post-operative cage cards.

To correct and prevent a recurrence, a protocol amendment was submitted and approved to add the individual to the protocol as a surgeon. The Principal Investigator will verify that personnel from the collaborating laboratory are approved on the protocol before they begin manipulating animals.

The animals involved in this incident were supported by NIH funding. No significant costs associated with this event were identified, and funds will be returned if associated costs are identified.

OLAW appreciates the consideration of this matter by the University of Texas Health Science Center at Houston, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW agrees that appropriate corrective and preventive actions were taken. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S S Digitally signed by Brent C. Morse

Date: 2022.03.02 07:52:23 -05'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

A3413-3F

UTHealth

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

February 7, 2022

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 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) (6) (6) to you on January 31, 2022.

On January 5, 2022, the AWC received a report of unapproved personnel manipulating animals. Two cages of mice underwent an intracranial injection of tumor cells. One cage of mice was subjected to the intracranial injection procedure on December 9, and the second cage on December 31, 2021. Although the surgical procedure is approved on the protocol, the individual who performed the procedures was not approved on the protocol as a surgeon. The individual responsible for this incident is appropriately gualified and trained and has completed all the institutional training courses, including the Aseptic Surgical Techniques-Rodents. The individual has also been certified as an independent surgeon to perform the intracranial injection procedure by the Center for Laboratory Animal Medicine and Care and the AWC. No clinical consequences resulted from this incident as the mice were bright, alert, and active with normal food and water intake. The post-surgical procedural monitoring, care, and analgesic administration was as approved on the protocol and were properly documented on the post-operative cage cards. Upon discovering this incident, a protocol amendment was submitted to add the individual to the protocol as a surgeon. The amendment was submitted on January 5 and approved on January 7, 2022. Because this is a collaborative project, the Principal Investigator will verify that personnel from the collaborating laboratory are approved on the protocol before they begin manipulating animals.

The animals involved in this incident were supported by NIH funding (5R35GM138264-02). No significant costs associated with this event were identified, and funds will be returned if associated costs are identified.

713.500.3544 phone 713.500.3059 fax 7000 Fannin St., UCT-1732, Houston, TX 77030 Brent Morse, D.V.M., DACLAM Assurance A3413-01 February 7, 2022 Page 2 of 2.

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

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

Sincerely,

1.14

(b) (6)

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

MRB/tsl

cc: Dr. Juan Herrera, IACUC Chair

AWC Office

Obtained by Rise for Animals. Uploaded to Animal Research Laboratory Overview (ARLO) on 02/15/2023

(b) (6)

Wolff, Axel (NIH/OD) [E]

| From: | OLAW Division of Compliance Oversight (NIH/OD) |
|----------|--|
| Sent: | Wednesday, February 23, 2022 8:05 AM |
| То: | (b) (6) |
| Cc: | OLAW Division of Compliance Oversight (NIH/OD) |
| Subject: | RE: OLAW Response to Final Reports - Case A3413-01 |

Thank you for these reports. We will respond soon.

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

 From:
 (b) (6)

 Sent: Friday, February 18, 2022 12:23 PM

 To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; 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>; Herrera, Juan <Juan.Herrera@uth.tmc.edu>;

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Subject: [EXTERNAL] OLAW Response to Final Reports - Case A3413-01 Importance: High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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

Good Morning, Dr. Morse,

I have attached three PDFs concerning the above-referenced. Please advise if you have any issues with receiving the attachment.

Thanks and regards,





Initial Report of Noncompliance

By: BCM

Date: 2/2/2022

Time: Voicemail

| Name of Person reportir | ng: (b) (6) |
|-------------------------|-------------|
| Telephone #: | (b) (6) |
| Fax #: | |
| Email: | |
| | |

 Name of Institution:
 __Univ. of Texas Health (Houston)_____

 Assurance number:
 __A3413_____

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

Intracranial tumor cell injection performed on mice on December 9, and 31, 2021 (2 cages) by person who was not approved but was fully trained. No negative outcomes for animal welfare.

Species involved: Mus musculus Personnel involved: Researcher Dates and times: see above Animal deaths: no

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

Protocol amendment approved to add surgeon.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

OFFICE USE ONLY Case #_____