



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

June 16, 2021

Re: Animal Welfare Assurance
#A3518-01 [OLAW Case 2B]

Maja Mataric, Ph.D.
Interim Vice President of Research
University of Southern California
3720 South Flower St., CUB (b) (4)
Los Angeles, CA 90089-0706

Dear Dr. Mataric,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 10, 2021 letter, received in our office on June 7th, reporting noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Southern California. Your letter supplements the information provided in the initial telephone report on March 9, 2021. According to the information provided it is understood that a mouse underwent survival cranial window surgery in May 2019. This procedure was approved as a non-survival surgery on this IACUC protocol. Additionally, documentation on the post-operative cage card indicated that analgesics were not administered as would be required for survival surgery. Upon further investigation, several other mice between 2017-2020 also had unapproved survival surgeries. The related protocols were supported by PHS funds.

The IACUC voted to suspend the lab from work with laboratory animals on all protocols. The following corrective and preventive actions were taken:

1. The PI was required to provide a written explanation to the IACUC why the mouse found on February 3, 2021 was recovered and retained by the laboratory for nearly 2 years.
2. The PI and laboratory staff were required to inventory all animals and cages housed in the animal facility and assess their purpose in research. The PI submitted the results of this inventory report to the IACUC, including findings and actions taken to better manage the colony and prevent overlooking animals in the future.
3. The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted on all protocols from 2017 through 2021.
4. The PI was required to identify a Co-Investigator or assign a Study Contact for each IACUC protocol who will assume responsibility and oversight of each individual project.
5. The PI was required to perform a review of all of their IACUC protocols with every member of laboratory staff listed on a given protocol and ensure all protocols were up to date and adequately reflected current experimental goals and procedures.
6. Upon completion of the updates, each laboratory member was required to sign off and attest that they have fully read and understood each protocol and that they will only carry out procedures that are described in the protocol.

7. The PI was required to acknowledge that any data obtained from the non-compliant surgeries described in this letter was collected without IACUC approval and that, if published or distributed in any form, the data must not be associated with any statement indicating IACUC approval.

The IACUC has voted to lift the suspension. To date there have been no other instances of noncompliance in this principal investigator's laboratory.

OLAW appreciates the consideration of this matter by the University of Southern California, which was 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, correct the non-compliance, and prevent recurrence. Please note that the grant(s) should not be charged for any of the unapproved activities. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2021.06.16 08:37:20 -04'00'

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

cc: IACUC contact

May 10, 2021

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

This is to report a suspension of animal use activity at the University of Southern California (animal welfare assurance number D16-00320/A3518-01). A preliminary report was provided to you on March 9th, 2021. The IACUC protocols for this work were associated with PHS funding (#R01NS090904, R01NS100459, R01AG023084, R01NS034467, RF1AG039452, and R01NS117827).

On February 3rd, 2021, a mouse with a cranial window implant was reported to veterinary staff for signs of infection around the implant. It was noted on the associated cage card that this mouse underwent cranial window surgery in May 2019. This procedure was approved as a non-survival surgery on this IACUC protocol. Additionally, documentation on the post-operative cage card indicated that analgesics were not administered as would be required for survival surgery. Billing for the care of this mouse was transferred to non-federal funding sources.

Upon further investigation, past sick case reports showed several other mice between 2017-2020 also had similar signs reported and cranial window implant failures. All protocols under which these survival surgeries were performed were approved for non-survival surgeries.

The IACUC discussed these incidences at a convened meeting with a quorum on February 17, 2021 and voted to suspend this lab from work with laboratory animals on all protocols for 90 days. The following corrective actions were required by the IACUC at the time of suspension:

1. The PI was required to provide a written explanation to the IACUC why the mouse found on February 3, 2021 was recovered and retained by the laboratory for nearly 2 years.
2. The PI and laboratory staff were required to inventory all animals and cages housed in the animal facility and assess their purpose in research. The PI submitted the results of this inventory report to the IACUC, including findings and actions taken to better manage the colony and prevent overlooking animals in the future.
3. The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted on all protocols from 2017 through 2021.

4. The PI was required to identify a Co-Investigator or assign a Study Contact for each IACUC protocol, who will assume responsibility and oversight of each individual project.
5. The PI was required to perform a review of all of their IACUC protocols with every member of laboratory staff listed on a given protocol, and ensure all protocols were up to date and adequately reflected current experimental goals and procedures.
6. Upon completion of the updates, each laboratory member was required to sign off and attest that they have fully read and understood each protocol, and that they will only carry out procedures that are described in the protocol.
7. The PI was required to acknowledge that any data obtained from the non-compliant surgeries described in this letter was collected without IACUC approval and that, if published or distributed in any form, the data must not be associated with any statement indicating IACUC approval.

The Principal Investigator (PI) provided a complete response for all of the required items by April 2nd, 2021. He acknowledged the oversight on the multiple protocols, but pointed out that he had approval on another protocol for cranial window implant as a survival surgery, and that his laboratory staff mistakenly thought all protocols were similarly approved. In addition, the PI notified the IACUC that his laboratory's imaging facility booking records did not show that anyone from his laboratory carried out a cranial implant procedure in May 2019. He suggested that this finding was due to misplacement of an older cage card on a more recent experimental mouse. His laboratory has since instituted practices that include more stringent oversight of cage cards. The PI also requested that the suspension be lifted earlier than 90 days.

The written response from the PI and training documentation for the staff members was reviewed at the full IACUC meeting on April 7th, 2021. The response was deemed acceptable by the committee who voted to lift the suspension. To date there have been no other instances of noncompliance in this principal investigator's laboratory.

Should you have any questions about these incidents or the corrective actions outlined above, please contact me.

Sincerely,

(b) (6)

Maja Matarić
Interim Vice President of Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 9, 2021 7:22 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letter of Report

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Monday, June 7, 2021 2:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Letter of Report

Hello,

Please see the attached report for a preliminary report made on March 9th.

Best,





Initial Report of Noncompliance

By: BCM

Date: 3/9/2021

Time: 2:35

Name of Person reporting: (b) (6)
 Telephone #: (b) (6)
 Fax #:
 Email:

Name of Institution: Univ. of So. Cal. (USC)
 Assurance number: A3518

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

What happened?

Survival cranial window surgery performed on mice. Only non-survival surgery was authorized. No record of post-op analgesia administration. One surgery performed in May 2019. Six others performed 2017 – 2019. Seven mice total.

Species involved: mus musculus
 Personnel involved: Researcher
 Dates and times: 2017 - 2019
 Animal deaths: No

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

Suspended protocol for 90 days starting February 17, 2021.

Projected submission to OLAW of final report from Institutional Official:

< 60 days. To be reported to funding component by OLAW. Advised USC not to charge grant for unapproved surgeries and aftercare unless husbandry and vet care authorized by funding component. Advised to send grant #.

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