



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

July 23, 2021

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

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 July 14, 2021 letter 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 May 10, 2021. According to the information provided it is understood that on March 18, 2021, two rats were found lethargic and exhibiting signs of severe pain. The post-operative cards on the cages were incomplete, missing pertinent information including analgesic administration. The rats were immediately administered both Buprenorphine SR and Meloxicam by the veterinarian. One rat died and the other survived to the experimental endpoint. Two other rats had also undergone the same surgery but did not show signs of pain. These rats also survived to endpoint and were given pain meds by the veterinarian. The related protocols were supported by PHS funds but billing for the care of these rats was transferred to non-federal funding sources.

Corrective and preventive actions: The IACUC discussed these incidences at a convened meeting with a quorum 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 Principal Investigator (PI) was required to provide a written explanation to the IACUC why the research staff thought it was appropriate and humane to perform painful major survival surgery on animals and not administer appropriate pain medication.
2. The PI and laboratory staff working with animals were required to complete training in anesthesia, analgesia, surgical skills, and compliance, including one extra AALAS training course on pain management.
3. The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted in the last two years.
4. The PI was required to amend the protocol to clarify experimental endpoints and adverse events.

The PI provided a complete response to all of the required items. The response from the PI, including training documentation for the PI and lab members, was reviewed at the full IACUC meeting. The response was deemed acceptable by the committee who voted to lift the suspension early. 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. 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: 2021.07.23 13:34:14 -04'00'

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

cc: IACUC contact

July 14, 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 May 10th, 2021. The IACUC protocols for this work were associated with PHS funding (#5R01EY017918-14).

On March 18, 2021, 2 rats were found lethargic and exhibiting signs of severe pain. The post-operative cards on the cages were incomplete, missing pertinent information including analgesic administration. The rats were immediately administered both Buprenorphine SR and Meloxicam by the veterinarian. One rat died and the other survived to the experimental endpoint. 2 other rats had also undergone the same surgery but did not show signs of pain. These rats also survived to endpoint and were given pain meds by the veterinarian.

Billing for the care of these rats was transferred to non-federal funding sources.

The IACUC discussed these incidences at a convened meeting with a quorum on April 21, 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 Principal Investigator (PI) was required to provide a written explanation to the IACUC why the research staff thought it was appropriate and humane to perform painful major survival surgery on animals and not administer appropriate pain medication.
2. The PI and laboratory staff working with animals were required to complete training in anesthesia, analgesia, surgical skills, and compliance, including one extra AALAS training course on pain management.
3. The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted in the last 2 years.

4. The PI was required to amend the protocol to clarify experimental endpoints and adverse events.

The PI provided a complete response to all of the required items by June 9, 2021. In the response the PI acknowledged and apologized for the oversight of the laboratory but pointed out that the animals had in fact received some analgesic pre-operatively, though this was inadequate.

The totality of the response from the PI, including training documentation for the PI and lab members was reviewed at the full IACUC meeting on June 16, 2021. The response was deemed acceptable by the committee who voted to lift the suspension early. 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 at (b) (6). Note, any follow-up regarding this should be directed to Dr. Ishwar Puri, the USC Vice President of Research, effective August 1, 2021.

Sincerely,

(b) (6)

Maja Matarić
Interim Vice President of Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 19, 2021 9:20 AM
To: Brett Thomas Lund
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Suspension of animal use activity

Thank you for this report, Dr. Lund. We will send a response soon. Please ensure that the suspension is also reported to the NIH funding component.

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

From: Brett Thomas Lund <blund@usc.edu>
Sent: Thursday, July 15, 2021 8:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Maja Mataric <mataric@usc.edu>; Ishwar Puri, Vice President of Research <vice.president.research@usc.edu>; (b) (6)
(b) (6)
Subject: Suspension of animal use activity

Dear Dr. Morse

Please find attached details relating to a suspension of animal use activity at the University of Southern California.

Should you have any questions please do not hesitate to contact me.

Brett T. Lund, Ph.D.
Director, Institutional Animal Care and Use Committee
University of Southern California

Associate Professor, Neurology
Keck School of Medicine
University of Southern California
McKibben Annex, (b) (4)
1333 San Pablo St,
Los Angeles, CA 90033

Tel: (b) (6)



Initial Report of Noncompliance

By: BCM

Date: 5/10/2021

Time: 2:05

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: NEI

Was funding component contacted (if necessary): No

What happened?

Survival surgery performed on two rats. Post-op analgesia administration not per protocol. Only NSAIDS given.

Species involved: rat

Personnel involved: Research staff

Dates and times: 3/18/2021

Animal deaths: No

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

Suspended protocol starting 4/21/2021.

Projected submission to OLAW of final report from Institutional Official:

Will retrain lab personnel and require protocol amendment to clarify endpoints.

< 60 days. Advised USC not to charge grant during suspended period unless authorized by funding component for husbandry and vet care.

OFFICE USE ONLY

Case #