



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

August 20, 2021

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

Dr. Ishwar Puri
Vice President of Research
University of Southern California
3720 South Flower St., CUB (b) (4)
Los Angeles, CA 90089-0706

Dear Dr. Puri,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 11, 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 January 13, 2021. According to the information provided it is understood that on December 4, 2020, lab members were found to be performing euthanasia of mice using a closed container in which animals were in direct contact with isoflurane-soaked napkins. A DAR veterinary staff member instructed the principal lab member to stop using this method immediately as the direct contact with the isoflurane can be aversive and painful to the animals. The procedure room is equipped with both an isoflurane vaporizer and CO2 chamber for use. Thirty minutes later, the DAR veterinary staff member re-entered the room to see the principal lab member using the same procedure despite the direction to stop this method immediately. The associated activity was PHS funded.

Corrective and preventive actions included:

1. The PI and all lab members handling animals must undergo a PI/non-compliance training and euthanasia policy refresher training with the research integrity specialist or a DAR veterinarian.
2. All lab members euthanizing animals must contact DAR veterinary staff to observe the procedure until it is deemed that the appropriate methods are being used to euthanize the animals.
3. The principal lab member was suspended from all animal work under all IACUC protocols for a period of 3 months.

After completion of the requirements for re-instatement of the protocol, the IACUC voted to lift the suspension on March 17th, 2021. 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. Due to the repeat nature of the incident, OLAW advises unannounced lab visits to ensure that the unauthorized euthanasia method is not being used. 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: 2021.08.20 08:42:56 -04'00'

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

cc: IACUC contact



August 11, 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 10, 2021. The IACUC protocol for this work was associated with PHS funding (5P01AG026572).

On December 4, 2020, lab members were found to be performing euthanasia of mice using a closed container in which animals were in direct contact with isoflurane-soaked napkins. A DAR veterinary staff member instructed the principal lab member to stop using this method immediately as the direct contact with the isoflurane can be aversive and painful to the animals. The procedure room is equipped with both an isoflurane vaporizer and CO2 chamber for use. Thirty minutes later, the DAR veterinary staff member re-entered the room to see the principal lab member using the same procedure despite the direction to stop this method immediately.

The IACUC discussed this matter at a convened meeting with a quorum on December 9, 2020 and voted to suspend the lab member from working 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 and all lab members handling animals must undergo a PI/non-compliance training and euthanasia policy refresher training with the research integrity specialist or a DAR veterinarian.
2. All lab members euthanizing animals must contact DAR veterinary staff to observe the procedure until it is deemed that the appropriate methods are being used to euthanize the animals.
3. The principal lab member was suspended from all animal work under all IACUC protocols for a period of 3 months.

The Principal Investigator (PI) provided a complete response to all of the required items on January 7, 2021. In this response the PI included a letter from the principal lab member who took responsibility for what occurred, profusely apologized and assured the committee this matter would not happen again. The PI assured the committee that the matter would be dealt with and that all personnel would

The written response from the PI and the principal lab member, along with training documentation for all laboratory personnel was reviewed at the full IACUC meeting on March 17th, 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.

Sincerely,

(b) (6)

Ishwar K. Puri, Ph.D.
Vice President of Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 13, 2021 7:18 AM
To: Ishwar Puri, Vice President of Research
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Suspension of animal use activity at the University of Southern California

Thank you for this report. We will send a response soon.

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

From: Ishwar Puri, Vice President of Research <vice.president.research@usc.edu>
Sent: Wednesday, August 11, 2021 7:47 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: Suspension of animal use activity at the University of Southern California
Importance: High

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.

Sincerely,

Ishwar. K Puri
Vice President of Research
University of Southern California

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, August 4, 2021 10:18 AM
To: Walker, Keri (NIH/OD) [E]
Subject: RE: [External] OLAW Cases A3518-2A & 2B - Update Requested

Hi Keri,

Looks like we never got a response to this reminder for case -2A. Please send another reminder to (b) (6) and state that "Dr. Morse needs a response by August 20th." Thank you.

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

From: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Sent: Wednesday, June 9, 2021 8:46 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: [External] OLAW Cases A3518-2A & 2B - Update Requested

Thank you, will do!

Keri

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Wednesday, June 9, 2021 8:42 AM
To: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Subject: RE: [External] OLAW Cases A3518-2A & 2B - Update Requested

Thank you Keri. Yes, have her send a response, please. It was protocol noncompliance and it was PHS-funded. Thank you. (Case -2A)

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

From: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Sent: Monday, June 7, 2021 2:33 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: FW: [External] OLAW Cases A3518-2A & 2B - Update Requested

Hello!

Please advise on how to respond.

Thanks!

Keri

From: [REDACTED] (b) (6)
Sent: Monday, June 7, 2021 2:26 PM
To: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Subject: RE: [External] OLAW Cases A3518-2A & 2B - Update Requested

Hello Keri,

Thank you for the reminder, I have sent the final report for the second preliminary report item to the email you provided. The first was only a suspension of a person, not an animal activity, does OLAW still need a report for that?

Best,

[REDACTED] (b) (6)

From: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Sent: Monday, June 7, 2021 7:52 AM
To: [REDACTED] (b) (6)
Subject: [External] OLAW Cases A3518-2A & 2B - Update Requested

Good morning [REDACTED] (b) (6)

I am writing you on behalf of the Office of Laboratory Animal Welfare (OLAW), Division of Compliance Oversight (DCO) to follow up on two preliminary reports initially submitted via phone call by you on January 13th, 2021 and March 9th, 2021. The first incident involved mice being euthanized by isoflurane administration not approved in the protocol. The second involved survival cranial window surgeries performed on mice. Please send an update or final report regarding these incidents to olawdco@od.nih.gov within the next 10 days. Should you have any questions feel free to contact me.

Thank you in advance,

Keri Walker

*Keri Walker
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare*



Initial Report of Noncompliance

By: BCM

Date: 1/13/2021

Time: 3:56

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: NIA

Was funding component contacted (if necessary):

What happened?

3 mice euthanized by drop method of isoflurane administration. Not approved in protocol.

Species involved: mus musculus

Personnel involved: Researcher

Dates and times: Dec 4, 2020

Animal deaths:

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

Suspended employee for 3 months from working with animals. Retrain employee and other lab members in proper rodent euthanasia.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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Case #