



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

January 26, 2022

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

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 January 13, 2022 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 September 21, 2021. According to the information provided it is understood that unapproved surgeries had been performed on rats, and that the correct anesthetics and analgesics were not administered to animals according to the approved IACUC protocols. This was a PHS-supported study.

At a convened meeting with a quorum on September 15, 2021, the IACUC voted to suspend this lab from work with laboratory animals on all protocols for 90 days.

To correct and prevent the issue at hand the PI and lead staff member working with animals were required to attend an in-person PI and compliance training, and all laboratory members were required to take multiple pertinent AALAS non-compliance training modules. The PI acknowledged that any data obtained from the non-compliant surgeries described in this letter were collected without USC IACUC approval and could not be published or distributed in any form. The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted in the last two years. The PI was required to amend the protocol to include all the surgeries to be performed and to ensure the use of the correct anesthetics and analgesics, and to meet with their laboratory to critically review all IACUC protocols and discuss the importance of reading the protocols as approved prior to performing procedures. The PI was required to submit a signed record that each staff member has reviewed and understands the IACUC protocols as written.

The response from the PI 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. Please be sure that any expenses associated with the unauthorized surgeries were not charged to the grant. We appreciate being informed of this matter and find no cause for further action by this office.

Page 2 – Dr. Puri  
January 26, 2022  
OLAW Case A3518-2E

Sincerely,

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

**S**

Date: 2022.01.26 09:06:19 -05'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact



USC University of  
Southern California

A3518-2E  
**OFFICE OF RESEARCH**  
Ishwar K. Puri, Ph.D.  
Vice President of Research  
vpres@usc.edu

January 13, 2022

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 September 21, 2021. The IACUC protocols for this work were associated with PHS funding (R01DK121531 & R01DK118910).

On August 16, 2021, during IACUC inspections of surgical records, it was discovered that unapproved surgeries had previously been performed on rats, and that the correct anesthetics and analgesics were not administered to animals according to the approved IACUC protocols. All animals had been euthanized prior to the inspection date so no billing for the care of these rats was changed.

The IACUC discussed these incidences at a convened meeting with a quorum on September 15, 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:

The PI and lead staff member working with animals were required to attend an in-person PI and compliance training, and all laboratory members were required to take multiple pertinent AALAS non-compliance training modules.

The PI had to acknowledge that any data obtained from the non-compliant surgeries described in this letter were collected without USC IACUC approval and could not be published or distributed in any form.

The PI was required to provide the IACUC with all surgical records for survival and non-survival surgeries conducted in the last 2 years.

The PI was required to amend the protocol to include all the surgeries to be performed and to ensure the use of the correct anesthetics and analgesics, and to meet with their laboratory to critically review all IACUC protocols and discuss the importance of reading the protocols as approved prior to performing procedures. The PI was required to submit a signed record that each staff member has reviewed and understands the IACUC protocols as written.

The PI provided a complete response to all of the required items. In this response the PI acknowledged the issue and profusely apologized for the oversight of the laboratory. 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 November 10, 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 do not hesitate to either contact me or the IACUC director at [iacuc@usc.edu](mailto:iacuc@usc.edu).

Sincerely,

(b) (6)

Ishwar K. Puri, Ph.D.  
Vice President of Research  
University of Southern California

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, January 14, 2022 7:51 AM  
**To:** Ishwar Puri, Vice President of Research  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: NIH OLAW (OLAW Division of Compliance Oversight (NIH/OD))

Thank you for this report, Dr. Puri. 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:** Thursday, January 13, 2022 6:23 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Institutional Animal Care and Use Committee <iacuc@usc.edu>; Brett Thomas Lund <blund@usc.edu>  
**Subject:** [EXTERNAL] NIH OLAW (OLAW Division of Compliance Oversight (NIH/OD))  
**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.

Hello,

Please find the attached letter.

Sincerely,

Ishwar K. Puri, Ph.D.  
Vice President of Research  
University of Southern California



## Initial Report of Noncompliance

By: BCM

Date: 9/21/2021

Time: 1:00

Name of Person reporting: Brett Lund, PhD, Chair

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?

Surgery performed on rats without IACUC approval.

Species involved: rat

Personnel involved: Research staff

Dates and times: Suspended on 9/15/2021

Animal deaths: No

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

Suspended protocol starting 9/20/2021.

Projected submission to OLAW of final report from Institutional Official:

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

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Case #