

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

February 28, 2022

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

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 February 22, 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 on August 24, 2021, during semiannual IACUC inspections of animal facilities, multiple cages of mice were found to be receiving special diet. The use of a special diet was not approved on the associated IACUC protocol, nor any protocol in this laboratory. The laboratory was told by the inspectors that they must stop the unapproved research. This was a PHS-supported study.

Corrective and preventive actions included the IACUC reminding the Principal Investigator that they must not conduct unapproved animal research, and that they must submit an amendment for any new research on existing protocols prior to beginning experiments. The PI apologized for the oversight in this matter and assured the committee that this would not happened again. In addition, the laboratory confirmed that the animals used in this unapproved research were euthanized and that no data was collected. Subsequent to this communication an amendment for the use of special diet was received and approved by the IACUC. Up to the date of your letter there had been no other instances of noncompliance in this 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 feeding of the unauthorized special diet were not charged to the grant. 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: 2022.02.28 08:54:54 - 05'00'

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

cc: IACUC contact

13518-01F



OFFICE OF RESEARCH

Ishwar K. Puri, Ph.D. Vice President of Research vpres@usc.edu

February 22, 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 communication is to report unapproved animal research 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 protocol for this work was associated with PHS funding (1RF1AG061834-01).

On August 24, 2021, during semiannual IACUC inspections of animal facilities, multiple cages of mice were found to be receiving special diet. The use of a special diet was not approved on the associated IACUC protocol, nor any protocol in this laboratory. The laboratory was told by the inspectors that they must stop the unapproved research.

The IACUC discussed this matter at a convened meeting on September 15, 2021, at which a quorum of members was present. The committee voted to remind the principal investigator that they must not conduct unapproved animal research, and that they must submit an amendment for any new research on existing protocols prior to beginning experiments.

The Principal Investigator (PI) provided a complete response to the IACUC on October 10, 2021. The PI apologized for the oversight in this matter and assured the committee that this would not happened again. In addition, the laboratory confirmed that the animals used in this unapproved research were euthanized and that no data was collected. Subsequent to this communication an amendment for the use of special diet was received and approved by the IACUC.

The written response from the PI was reviewed at the full IACUC meeting on October 18, 2021, and the closure of the matter discussed at the full IACUC meeting on January 21, 2022. The initial response, and all follow-up activities, were deemed acceptable by the committee. Up to the date of this letter there have been no other instances of noncompliance in this 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:

Wednesday, February 23, 2022 8:38 AM Ishwar Puri, Vice President of Research

To: Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: [EXTERNAL] OLAW Letter [WARNING: UNSCANNABLE EXTRACTION FAILED]

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: Tuesday, February 22, 2022 6:09 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Brett Thomas Lund <blund@usc.edu>; Institutional Animal Care and Use Committee <iacuc@usc.edu>

Subject: [EXTERNAL] OLAW Letter [WARNING: UNSCANNABLE EXTRACTION FAILED]

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

Morse, Brent (NIH/OD) [E]

From:

Morse, Brent (NIH/OD) [E]

Sent:

Wednesday, February 16, 2022 10:06 AM

To:

Brett Thomas Lund

Subject:

Open OLAW case from September?

Importance:

High

Good morning Dr. Lund,

We have an open case reported by you on September 21, 2021. It involved 35 cages of mice fed a high fat diet without IACUC approval. Lab was sent a "cease and desist" notice. Do you have a final report available? If not, please send an interim report. Thank you.

Best regards, Brent Morse

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

A3518-2F



Initial Report of Noncompliance

By: BCM

Date:	9/21/2021	Time: 1:00
Name	of Person repor Telephone #: Fax #: Email:	ting: Brett Lund, PhD, Chair (b) (6)
Name Assur	of Institution: ance number:	Univ. of So. Cal. (USC) A3518
Fund	ing component:	PHS funded activity?yes nent contacted (if necessary):
What l	appened?	
		high fat diet without IACUC approval. Lab continued feeding diet even b. IACUC then sent lab a "Cease and Desist" notice.
Pers Date	es and times:?	No animal welfare issues
Project	ed plan and scl	nedule for correction/prevention (if known):
Project	ed submission	to OLAW of final report from Institutional Official:
	ays. Advised U roposal.	SC data from unapproved study should not be used for publication or for
	E USE ONLY #	