



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) 402-7065

January 6, 2020

Re: Animal Welfare Assurance
A3416-01 [OLAW Case 2F]

Pramod Khargonekar, Ph.D.
Vice Chancellor for Research
University of California-Irvine
(b) (4) Aldrich Hall
Irvine, CA 92697-3175

Dear Dr. Khargonekar,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California, Irvine. According to the information provided, OLAW understands that as part of a routine annual review of an approved protocol, it was reported that a rat died after being left in a recovery cage in a procedure room instead of being returned to the home cage in the vivarium. It was stated that this animal activity was PHS-funded.

It is understood that the corrective action plan included discussing the incident with all lab members during lab meetings and instructing all staff researchers and students to always check the procedure room at the end of the day. The PI has instituted procedures for documenting the training of all members of the research team. In addition, the lab will implement a recording system to list each lab member's responsibilities and indicate when the individual has completed each task. All members of the research team must complete remedial training.

OLAW appreciates the prompt consideration of this matter by the University of California, Irvine, 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 and correct the deficiency, and to prevent recurrence. We do emphasize that all PIs should be advised to not wait until a protocols Annual Review to report an animal welfare incident. This should be done promptly so that the IACUC can fulfill its responsibilities in a timely manner. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



A3416-2F
Office of Research
141 Innovation, Suite 250
Irvine, CA 92697-7600

December 18, 2019

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: University of California, Irvine - Animal Welfare Assurance # D16-00259

Dear Dr. Morse:

The University of California, Irvine (UCI) is reporting an animal welfare issue involving a rat on a federally-funded study. The incident was reported as part of a routine Annual Review of the approved protocol (AUP-18-145). Funding for the project is provided by NIH grant number R44 EY027654.

In the Annual Review, the Principal Investigator reported that a single rat was accidentally left in a recovery cage in a procedure room; other rats in the same cohort were returned to their home cages and vivarium housing room. The animal left in the procedure room was later found dead.

The UCI IACUC discussed the Annual Report and determined that the incident necessitated reporting to OLAW as a condition that led to the death of an animal. Please note that this was an isolated incident, an unfortunate accident in an otherwise compliant laboratory.

The Principal Investigator and her staff took the following actions in response to this situation:

- The incident was discussed in depth with all members of the laboratory staff during routine lab meetings. The seriousness of the event was emphasized to all members of the research team.
- All staff researchers and students were instructed to always check the procedure room at the end of the day and to notify others in the laboratory if they could not complete this task.
- The Principal Investigator has instituted procedures for documenting the training of all members of the research staff. IACUC members routinely review such records during semi-annual laboratory inspections.

The IACUC discussed the PI's actions at a subsequent convened meeting of the IACUC and determined the following additional actions were necessary to correct and prevent recurrence of this event:

Brent Morse, D.V.M.
Office of Laboratory Animal Welfare
12/18/19

- The lab will implement a recording system, either paper-based or computerized, to list each lab member's responsibilities and indicate when the responsible individuals have completed each task.
- All members of the research team must complete remedial training.

Please contact me or the IACUC Chair if you have any questions or concerns regarding this matter.

Sincerely,

DocuSigned by:
[Redacted Signature] (b) (6)
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Pramod Khargonekar, Ph.D.
Vice Chancellor for Research

cc: Institutional Animal Care and Use Committee Chair Burley
Attending Veterinarian and Director Lindsell
Associate Vice Chancellor for Research (b) (6)
IACUC Administrator (b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 23, 2019 8:59 AM
To: IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: University of California Irvine D16-00259

Thank you for providing this final report (b) (6). We will send an official response soon.

Best regards, Brent Morse

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

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From: IACUC [mailto:iacuc@uci.edu]
Sent: Friday, December 20, 2019 12:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: University of California Irvine D16-00259

Please see attached compliance self-report.



Office of Research
Winter Administrative Recess - Dec 24, 2019 - Jan 1, 2020