



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

March 23, 2020

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

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 March 13, 2020 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 three live mice were found in a carcass bag due to a failure to ensure death by the protocol required secondary physical method following exposure to CO2 for euthanasia. This constitutes a repeat of the same incident for this laboratory.

The corrective actions consisted of counseling the laboratory staff and the student responsible, having the Principal Investigator (PI) and laboratory staff undertake online and hands-on retraining, having the PI and staff meet with Institutional Animal Care and Use Committee (IACUC) representatives and with the department chair to discuss this repeat noncompliance, and informing the laboratory of the consequences of another repeat of the same noncompliance. To prevent a recurrence, the laboratory was advised to conduct euthanasia in pairs and to take care when scheduling experiments around holidays.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

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Axel V. Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3416-2H



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

March 13, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 28092

RE: University of California, Irvine – Animal Welfare Assurance number D16-00259 (A3416-01)

Dear Dr. Morse,

The University of California, Irvine (UCI) is submitting this report of non-compliance involving inadequate euthanasia of mice on a federally funded study. Funding for the project is provided by NIH grant number R01HL096987.

On December 19, 2019, campus veterinarians alerted the IACUC office and the Principal Investigator of 3 adult mice found alive inside a carcass disposal bag. The Principal Investigator indicated that a graduate student had euthanized the animals with CO2 gas but had neglected to perform a secondary physical method (cervical dislocation as indicated in the approved protocol). The same Principal Investigator was previously cited for the same infraction in 2017, about which OLAW was notified by a preliminary report on 9/27/17 and a final report on 1/25/18. This recent recurrence in 2019 involved a different person than the person from the 2017 incident.

The Principal Investigator immediately instituted the following measures within his laboratory:

- With the graduate student involved in the latest incident, the Principal Investigator and his senior staff reviewed all euthanasia methods and experimental procedures as described in the approved protocol – the student was also informed that future recurrence can lead to his exclusion from animal research activities;
- All members of the laboratory research team were verified to have completed hands-on training by senior staff, in addition to completion of required online training modules;
- The Principal Investigator confirmed that all members in his lab had completed the required online training modules and had received in-person training by senior members of the research team. At the early phase of their research project, new lab members received in-person oversight and were instructed with proper protocols and procedures.

B. Morse, 3/13/20

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The IACUC discussed the incident and actions taken by the Principal Investigator at its convened meeting on January 9, 2020. While the PI took immediate corrective actions, the committee expressed concern that this repeat occurrence indicated a breakdown in sufficient oversight within the lab. Accordingly, the IACUC required additional sanctions to resolve the issue.

The following additional corrective actions and sanctions were imposed by the IACUC:

- Completion of the remedial online training in laboratory animal care and use was required for all members of the laboratory research team, including the PI;
- The PI and all members of the laboratory research team were required to meet with representatives of the IACUC and the PI's department chair to discuss the repeat noncompliance;
- The lab was informed that any additional recurrence of inadequate euthanasia of research animals will very likely result in suspension of the PI's animal-use protocol for a significant interval of time, during which all research activities involving live animals must cease.

At the compliance follow-up meeting conducted on February 14, 2020, representatives of the IACUC discussed the seriousness of inadequate euthanasia and the committee's concerns regarding repeat occurrences. Suggestions of various management practices were also provided to the PI and his senior staff, in an effort to prevent future recurrence. These suggestions included performing animal euthanasia in pairs of personnel, and careful planning when scheduling experiments around holidays. The lab was reminded that any further occurrence of inadequate euthanasia will likely result in suspension of the PI's animal use protocols.

All corrective actions were verified as completed at the IACUC meeting on March 12, 2020 and the IACUC considers the PI's actions appropriate and the matter resolved.

Please feel free to contact me or the IACUC Chair, Dr. Nancy Burley, if you have questions.

Sincerely,

DocuSigned by:

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Pramod Khargonekar, Ph.D.
Vice Chancellor for Research

cc: IACUC Chair N. Burley
Attending Veterinarian C. Lindsell

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 17, 2020 6:56 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Report -- University of California Irvine D16-00259

Thank you for this report, (b) (6) We will send a response soon.

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

From: IACUC <iacuc@uci.edu>
Sent: Monday, March 16, 2020 8:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Pramod Khargonekar <pramod.khargonekar@uci.edu>; Nancy Burley (UCI) <ntburley@uci.edu>; Claire Lindsell <claire.lindsell@uci.edu>; (b) (6)
Subject: Compliance Report -- University of California Irvine D16-00259

Please see attached compliance self-report.

A preliminary report was not submitted to OLAW with regard to this incident. All details, including correction plan, are included in the attached letter.

Sincerely, on behalf of the IACUC,

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