



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

May 17, 2019

Re: Animal Welfare Assurance
A3248-01 [OLAW Case 10]

Dr. Kimberly Ogden
Interim Vice President for Research
University of Arizona Health Sciences Center
P.O. Box 210066
Tucson, AZ 85721-0066

Dear Dr. Ogden,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 15, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Arizona, following up on an initial telephone report on February 28, 2019. According to the information provided, OLAW understands that four anesthetized mice were attached to a ventilator with no staff present.

The corrective actions consisted of notifying the Principal Investigator who informed the Institutional Animal Care and Use Committee (IACUC) that additional staff will be present during procedures to ensure adequate monitoring. All research personnel will be aware of the content of the protocol, will follow the protocol, and will not leave anesthetized animals unattended.

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

Sincerely,

(b) (6)

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

cc: IACUC Chair

May 15, 2019

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Morse,

The University of Arizona, in accordance with Assurance D16-00159 (A3248-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding failure to appropriately monitor anesthetized mice in a Principal Investigator's (PI) animal study protocol, entitled *Acute lung injury, mechanisms and intervention strategies*. This incident was first reported to Dr. Axel Wolff, OLAW, on 02/28/2019 via a telephone call by (b) (6).

On 02/25/2019 the IACUC Program received a report that a veterinary technician had come across 4 anesthetized mice connected to a ventilator that had been left unattended in a procedure room. The IACUC discussed the incident on 03/11/2019 and requested corrective actions from the PI.

The PI expressed in their response to the IACUC that this was an unfortunate incident and took responsibility for the noncompliance. The PI assured the IACUC that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

The following corrective action plan was implemented after the incident:

- The PI submitted correspondence to the IACUC, dated 03/04/2019, expressing regret for the noncompliant incident and that failure to appropriately monitor the mice as per the approved protocol was an oversight.
- The PI described corrective measures that had been implemented to prevent recurrence of an incident of this nature. The measures included ensuring that additional staff will be available in the future should a technician need to leave the room during a procedure.
- The PI assured the IACUC that all research staff will from now on carefully review and adhere to approved study protocols, and that anesthetized animals will not be left unattended.

At their meeting on 03/11/2019 the IACUC approved the corrective action plan implemented by the PI.

The University of Arizona is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions

[2019-007-N]

regarding this case, please contact (b) (6) at (b) (6) or
ORCR-IACUC@email.arizona.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Kimberly L Ogden, PhD
Interim Vice President for Research
Institutional Official
The University of Arizona

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 15, 2019 4:05 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: ORCR iacuc
Subject: RE: University of Arizona - Notice of Noncompliance

Thank you for providing this final report. 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

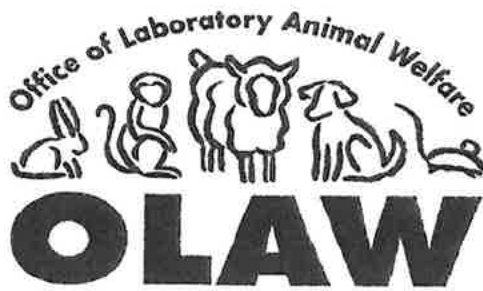
From: (b) (6)
Sent: Wednesday, May 15, 2019 3:05 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Subject: University of Arizona - Notice of Noncompliance

Dear Dr. Morse,

On behalf of Dr. Kim Ogden, I am forwarding a notice of Noncompliance.

Thanks,
(b) (6)





Initial Report of Noncompliance

By: am

Date: 2/28/19

Time: 11:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of Arizona

Assurance number: A3248

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

5 anesthetized mice on unattended ventilation

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

Counsel lab staff to always have someone present
so will have 2 people work with the mice

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____