



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

July 8, 2019

Re: Animal Welfare Assurance  
A3248-01 [OLAW Case 1N]

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 June 27, 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 21, 2019. According to the information provided, OLAW understands that wild type mice were being bred although this activity had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective actions consisted of counseling the Principal Investigator, separating the mice, informing research staff that IACUC approval is required for all animal activities, and amending the protocol to include breeding.

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,

(b) (6)

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

cc: IACUC Chair



THE UNIVERSITY OF ARIZONA

Research, Discovery  
& Innovation

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June 27, 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 breeding Wild Type mice in-house without approval from the IACUC in a Principal Investigator's (PI) animal study protocol, entitled *Investigating neurodevelopmental disorders in mouse models*. This incident was first reported to Dr. Axel Wolff, OLAW, on 02/21/2019 via a telephone call by (b) (6)

(b) (6)

On 02/21/2019 the IACUC Program received information that wild type mice were being bred on this protocol without prior IACUC review and approval. When contacted, the PI communicated that they were unaware that specific approval was required to breed wild type mice in-house, as they did have approval to breed several strains of mutant mice. PI staff separated all active wild type breeders that day. The IACUC discussed the incident on 03/11/2019 and requested corrective actions from the PI.

To address the situation, corrective actions were taken including the submission of an Animal Study Protocol Amendment to request approval for breeding wild type mice in-house. Approval was withheld until the IACUC reviewed and approved the PI's response, the corrective action plan and protocol amendment for the procedural change.

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 02/22/2019, expressing regret for the noncompliance incident and that exclusion of scientifically justified wild type breeding from the 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 informing all research staff of the IACUC's requirement for securing approval for all activities and procedures prior to work involving animals.
- The PI assured the IACUC that all research staff will from now on carefully review and adhere to approved study protocols.

- The PI submitted a request for a procedural change (Animal Study Protocol Amendment) to the protocol. The amendment describing the scientific justification for breeding wild type mice in-house was approved by the IACUC on 04/29/2019.

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 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]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, July 03, 2019 8:25 AM  
**To:** ORCR iacuc; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Ogden, Kimberly L - (ogden)  
**Subject:** RE: University of Arizona - Notice of Noncompliance

Thank you for providing this 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

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**From:** ORCR iacuc [mailto:ORCR-IACUC@email.arizona.edu]  
**Sent:** Tuesday, July 02, 2019 4:22 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** ORCR iacuc <ORCR-IACUC@email.arizona.edu>; Ogden, Kimberly L - (ogden) <ogden@email.arizona.edu>  
**Subject:** University of Arizona - Notice of Noncompliance

Hello Dr. Morse,

On behalf of our Institutional Official Dr. Kim Ogden, I am forwarding this Final Report of Noncompliance.

Thank you,

(b) (6)

(b) (6)





## Initial Report of Noncompliance

By: *aw*Date: *2/21/19*Time: *2:15*

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?

*Breeding mice w/out protocol, cannot breed wild type mice*Species involved: *mice*

Personnel involved:

Dates and times:

Animal deaths:

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

*Separate breeding pairs, amend protocol*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_