



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

August 9, 2022

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

Dr. Elizabeth Cantwell
Senior Vice President for Research
University of Arizona Health Sciences Center
P.O. Box 210066
Tucson, AZ 85721

Dear Dr. Cantwell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges your May 3, 2022 letter, received in our office on August 2, 2022, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Arizona. Your letter supplements the preliminary report submitted on November 9, 2020. According to the information provided it is understood that on November 2, 2020, it was determined that a lab was performing survival surgery on mice in a manner contrary to the approved IACUC protocol, using improper aseptic technique, and with incomplete surgical records. The lab manager was immediately educated on proper aseptic technique and the importance of following the approved protocol. The activity was not PHS funded.

Corrective and preventive actions:

- The PI stated that all surgical activities were immediately corrected, and an amendment submitted to ensure work is performed as described.
- The PI worked with veterinary staff to ensure training and that corrective measures that had been implemented to prevent recurrence of an incident of this nature. The measures included informing all research staff of the importance of correct tool sterilization for survival surgeries and adherence to the procedures as described on the approved IACUC protocol.

OLAW believes that the corrective and preventive measures put in place by the University of Arizona are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Brent C. Morse, DVM
Director

Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C. Morse -

5

Date: 2022.08.09 14:33:34 -04'00'

cc: IACUC contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Tuesday, August 9, 2022 3:25 PM
To: ecantwell@email.arizona.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); [REDACTED] (b) (6)
iacuc@email.arizona.edu
Subject: OLAW Case A3248-1X
Attachments: A3248-1X.pdf

Good afternoon Dr. Cantwell,

Attached please find Dr. Morse's final response to OLAW Case A3248-1X. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



5/3/21

Axel Wolff, MS, DVM
Deputy 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. Wolff,

The University of Arizona, in accordance with Assurance D16-00159 (A3248-01) and PHS Policy IV.F.3., provides this report of an incident of PI non-compliance which may have had a negative effect on the health and wellbeing of animals. This incident was first reported to OLAW on 11/9/20 via email, by the Assistant Director of the IACUC program. The activities were not funded by the PHS, however due to the serious nature and potential for animal harm, it was determined that an OLAW report is appropriate.

On 11/02/20, during the IACUC semi-annual inspection of animal facilities, it was discovered that a PI's lab was performing survival surgery on mice in a manner contrary to the approved IACUC protocol, using improper aseptic technique, and with incomplete surgical records. The lab manager was immediately educated on proper aseptic technique and the importance of following the approved protocol.

The following corrective action plan was implemented after the incident:

- The PI submitted correspondence to the IACUC, dated 11/9/20, expressing regret for the noncompliance incident and that all surgical activities were immediately corrected and an amendment submitted to ensure work is performed as described.
- The PI worked with University Animal Care (UAC) veterinary staff to ensure training and that corrective measures that had been implemented to prevent recurrence of an incident of this nature. The measures included informing all research staff of the importance correct tool sterilization for survival surgeries and adherence to the procedures as described on the approved IACUC protocol.

The IACUC discussed the incident on 12/14/20 and determined actions already taken by the PI are correct and that the incident could be closed once the amendment was approved. Approval was received on 4/19/21.

The IACUC determined that this was an isolated incident and not a programmatic failure.

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) or ORCR-IACUC@email.arizona.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Elizabeth Cantwell, PhD
Senior Vice President, Research and Innovation
Institutional Official
The University of Arizona

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, August 2, 2022 3:31 PM
To: (b) (6)
Subject: RE: Final report required by OLAW/NIH

Follow Up Flag: Follow up
Flag Status: Flagged

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

Sincerely, Brent Morse

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

From: (b) (6)
Sent: Tuesday, August 2, 2022 1:56 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] RE: Final report required by OLAW/NIH

Good morning,

Please see attached, and my apologies it was not received in a more timely manner.

(b) (6)

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Thursday, July 28, 2022 13:22
To: (b) (6)

Subject: [EXT]Final report required by OLAW/NIH

Importance: High

External Email

Hello (b) (6)

Please provide a final report for OLAW case-1X. If a final report is not available, an interim report, signed by the Institutional Official, is required by COB August 12, 2022. If I can be of assistance, please do not hesitate to contact me.

Sincerely, Brent Morse

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

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.

A3248-2X

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Friday, June 3, 2022 10:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: Final report needed

Good morning,

During a recent records check, we discovered that a preliminary report sent to us in November 2020 is still in need of a final report. This case is regarding a PI found to be using unapproved veterinary drugs, expired drugs, and poor aseptic technique for survival surgery. At your earliest convenience, please have the final report for this case sent to us.

Thanks,

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 2, 2021 7:22 AM
To: ORCR iacuc
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary reports for A3248-1S, 1U, 1W, 1X

Thank you for submitting these reports, (b) (6) We will send responses soon.

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

From: ORCR iacuc <ORCR-IACUC@email.arizona.edu>
Sent: Wednesday, March 31, 2021 3:23 PM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>; Cantwell, Elizabeth R - (ecantwell) <ecantwell@arizona.edu>; (b) (6)
(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
<olawdco@od.nih.gov>; (b) (6)
Subject: RE: preliminary reports for A3248-1S, 1U, 1W, 1X

Good afternoon,

Please find attached updates for the December 2019 (attachment 2019-022-N), June 2020 (attachment 2020-005-N), and one of the November 2020 (attachment 2020-010-N) reports.

The second November 2020 instance is still outstanding and we will forward the update as soon as it is completed.

Let me know if you have any questions.

Thank you!

(b) (6)

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Wednesday, March 24, 2021 08:04
To: Cantwell, Elizabeth R - (ecantwell) <ecantwell@arizona.edu>

Cc: ORCR iacuc <ORCR-IACUC@email.arizona.edu>

Subject: [EXT]preliminary reports for A3248-1S, 1U, 1W, 1X

External Email

Dear Dr. Cantwell,

I am writing you on behalf of the Office of Laboratory Animal Welfare (OLAW), Division of Compliance Oversight (DCO) to follow up on two preliminary phone reports submitted in December, 2019 and June, November 2020. The cases listed are: A3248-1S, 1U, 1W and 1X. Please send the final reports or an update to olawdco@od.nih.gov within the next 10 days. Should you have any questions feel free to contact us by phone or by email.

Regards and Thank you in advance,
Joan

*Joan Ward
Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-594-2506
wardjoa@od.nih.gov*

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 12, 2020 10:12 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Reports

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for these preliminary reports, (b) (6) I will open 5 separate case files and look forward to receiving individual reports from the IO after the IACUC has completed its investigations. In future, whenever feasible, please do not submit multiple reports in batches but rather provide a preliminary as soon as possible after the event, followed by the final. Be sure to include grant number(s) where applicable.

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

From: (b) (6)
Sent: Monday, November 9, 2020 8:23 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary Reports

Good afternoon,

I have instances of potential non-compliance, and an incident (not non-compliance) leading to animal harm to report. All were discovered or happened last week.

The following applies to all:

Contact: (b) (6)

Institution: The University of Arizona (UA)

Assurance: D16-00159 (A3248-01)

Each of the below situations involved a different PI.

1. 11/1 Incident, not non-compliance: On the morning of 11/1/20, Campus Agricultural Center ("Farm") staff, when reporting for morning husbandry duties, discovered that the secured sheep housing area of the Farm had been broken into, vandalized, and 2 sheep from the farm flock were injured. Farm staff immediately notified the veterinarian on duty, who evaluated the sheep and opted for immediate euthanasia. No other sheep were injured. Only UA/departmental funds were used to purchase the animals, and the sheep were indicated for use for agricultural purposes. Farm management has already implemented security measures additional to those that were already in place, and any damage that could cause injury has been repaired, and the situation is considered corrected. If needed, a final report from the IO can be submitted to OLAW after the next IACUC meeting in December.
2. 11/3 potential non-compliance: On 11/3/20, the IACUC office was notified by University Animal Care (UAC) personnel of a PI who had used more than their approved number of mice, as the PI attempted to order additional animals and was prevented from doing so. Animals were euthanized due to errors arising from unknowingly using the incorrect strain of mice previously ordered, in addition to excess breeding colony

animals. Funding is provided by the DoD, which will be notified concurrently with this notification. The PI is currently working with the IACUC to request additional animals to be approved, while working with UAC to ensure the breeding colony remains within its approved parameters. The PI has been given information on remaining compliant and the importance of adhering to the approved protocol for animal use. It is anticipated the PI will sufficiently address this issue before, and a final report from the IO can be submitted after, the next IACUC meeting in December.

3. 11/6a potential non-compliance: Discovered by AV as an IACUC inspector, during the course of semi-annual facility inspections by of PI lab locations, and inspection findings determined on 11/5/20 to be potential noncompliance. PI was found to be using unapproved veterinary drugs as well as an expired veterinary drug and poor aseptic technique for survival surgery, causing potential animal harm, and performed in the PI lab, which is not approved for surgical use. Funding is provided by the USDA, which does not require an individual report for this incident. The PI received immediate training and will receive additional training on aseptic technique, along with working with the IACUC to ensure only approved drugs and locations are in use. It is anticipated the PI will sufficiently address the issue before, and a final report from the IO can be submitted after, the next IACUC meeting in December.
4. 11/6b potential non-compliance: Discovered by UAC veterinarian as an IACUC inspector, during the course of semi-annual facility inspections of PI lab locations, and inspection findings determined on 11/5/20 to be potential noncompliance. PI was found to be using inappropriate aseptic surgical technique and recovery procedures on survival surgeries performed on mice and rats, causing potential animal harm, and failed to keep adequate surgical records. PI received immediate training and will receive additional training on proper survival surgical technique, recovery, and record keeping. Animals were funded by UA funds only. It is anticipated the PI will sufficiently address the issue before, and a final report from the IO can be submitted after, the next IACUC meeting in December.
5. 11/6c potential non-compliance: Discovered by UAC veterinarian as an IACUC inspector, during the course of semi-annual facility inspections of PI lab locations, and inspection findings determined on 11/5/20 to be potential noncompliance. PI was found to be using inappropriate aseptic surgical technique on survival surgeries performed on mice, causing potential animal harm. PI received immediate training and will receive additional training on proper aseptic surgical technique and will amend their protocol as needed. Animals were funded by VA funds, and proper notification has been made to the VA. It is anticipated the PI will sufficiently address the issue before, and a final report from the IO can be submitted after, the next IACUC meeting in December.

Please let me know if you have any questions or additional suggestions to provide to the PIs. As stated, we anticipate all will be addressed by the December meeting and the IO report will follow.

Thank you!

(b) (6)