



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 17, 2019

Re: Animal Welfare Assurance
#A3410-01 (OLAW Case 6Z)

Dr. Terry Magnuson
Vice Chancellor for Research
University of North Carolina at Chapel Hill
Campus Box 4000 (b) (4) South Building
Chapel Hill, NC 27599-4000

Dear Dr. Magnuson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of North Carolina at Chapel Hill, following up on an initial telephone report on February 14, 2019. According to the information provided, OLAW understands that an intubated pig on an anesthesia machine showed signs of distress/apnea due to the pressure relief valve being closed.

The immediate action taken upon discovery consisted of opening the valve and providing emergency veterinary care. The veterinarian recommended against continuing with the planned surgery and the pig was euthanized while under anesthesia. The laboratory staff was retrained in anesthesia induction and the Principal Investigator initiated use of a checklist for anesthetic procedures. The corrective actions were documented and submitted to and accepted by the Institutional Animal Care and Use Committee (IACUC).

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
Director of Animal Care and Use
IACUC Training & Compliance Manager
Robert Gibbens, D.V.M., USDA-APHIS-AC



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OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569
CAMPUS BOX 7193 F 919-966-8429
CHAPEL HILL, NC 27599-7115 iacuc@med.unc.edu

IACUC Animal Concern Report (ACR)

PHS Assurance #: D16-00256 (A3410-01)

Part I of this report serves to record preliminary information as it was presented to the Animal Concern Subcommittee (ACS) and includes ACS recommendations to the IACUC. Part II contains the IACUC's final recommendation to the Institutional Official (IO). This report is not final until Part II is signed and dated by the IO.

Acronyms:

Division of Comparative Medicine (DCM)
Principal Investigator (PI)
Office of Animal Care and Use (OACU)
Laboratory Animal Coordinator (LAC)

Training and Compliance Coordinator (TCC)
Training and Compliance Team (T&C)
Training and Compliance Manager (TCM)
Animal Concern Subcommittee (ACS)

ACR#: 2-19-1

NIH Grant #: 1 R01 DK107740-01

Reported by: PI Self-Report

Recorded by: TCM

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

1) **Summary of Events:** The PI self-reported an anesthetic complication that ultimately lead to the decision to euthanize a pig, while it was still under anesthesia. The incident occurred on 2/6/2019 and was promptly reported to the IACUC on the same day. According to the PI, and later confirmed by the DCM vets who intervened following the discovery, the animal had just been intubated and placed under general anesthesia and the lab members were preparing to move the animal to the operating room. The animal was noted to have a distended chest and abdomen, not breathing, and had no detectible heart sounds or ECG activity. Within ~ 1 minute, laboratory staff recognized that a pressure relief valve was closed on the anesthesia machine and it was opened. The lab staff and veterinarians provided immediate emergency interventions to stabilize the animal. Although the animal appeared to continue to improve, the DCM Vet recommended not entering into a survival surgery protocol. Euthanasia solution was given and a necropsy was performed.

The PI indicated that they would review management of the anesthesia circuit with emphasis on the valves that are adjusted during use with all named personnel on this protocol.

2) Findings of Fact, Conclusions, and ACS Recommendations:

a) Standards: (Cite regulation, standard, IACUC policy): N/A

b) Findings of Fact: Apparent human error during anesthesia induction led to a veterinary directed euthanasia of an animal under anesthesia.

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- c) **Subcommittee Recommendations:** OACU reported this incident to the ACS on 2/7/2019. The PI investigated the issue of anesthesia induction error and provided proposed actions to be taken to prevent future occurrences. The DCM Associate Director followed up to confirm that DCM Vet Services veterinarians and veterinary staff happened to be in the immediate area when this incident occurred. They were available to assist when there was a problem.

All ACS members agreed that, in addition to the PI's proposed actions, the PI shall retrain all lab members involved in anesthesia induction and provide documentation to the IACUC. The ACS agreed that no sanctions were warranted and suggested that the PI institute a checklist for anesthetic procedures to decrease the chance for similar errors in the future.

NIH funds were used to support this project. The ACS determined that no reimbursement was necessary.

The subcommittee recommendations along with DCM's proposed actions will be presented to the IACUC at the March 8, 2019 meeting.

- 3) **Required Report to OLAW:** ☒ Yes ☐ No
If Yes: Verbally Reported to OLAW by: TCM Date: 2/14/2019 Time: 10am, to AW
- 4) **Required Report to USDA:** ☒ Yes ☐ No
If Yes: Verbally Reported to USDA by: TH Date: 2/8/2019, with email follow-up on 2/11/19 at 10:06am

Part II: IACUC Conclusion and Report to Institutional Official

- 1) **IACUC Meeting Date and Closure:** The IACUC met on March 8, 2019 and accepted the ACS recommendations. The checklist for anesthetic machine operation is now a requirement of the laboratory for all survival and non-survival surgeries, regardless of the location where surgery is conducted. The PI shall provide a copy of the proposed checklist and the record of surgeon retraining upon receipt of this report. The checklists shall be maintained in the individual animal clinical records and be available for review by IACUC and/or USDA inspectors.

- 2) **IACUC Vote:**
- | | | | |
|----------------------------|-------------------------------------|------------------|-------------------------------------|
| Reportable | <input checked="" type="checkbox"/> | Not Reportable | <input type="checkbox"/> |
| Unanimous | <input checked="" type="checkbox"/> | Minority Opinion | <input type="checkbox"/> |
| Closed | <input checked="" type="checkbox"/> | Pending | <input type="checkbox"/> |
| NIH Reimbursement Required | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| | | No | <input checked="" type="checkbox"/> |
| | | NA | <input type="checkbox"/> |

Terry Magnuson, Ph.D.
Institutional Official

(b) (6)

Signature

5/14/2019

Date

CC:
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Principal Investigator
OACU Training and Compliance Coordinators and Director
Associate Vice Chancellor for Research
Office of University Counsel
IACUC Chair

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 17, 2019 6:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Written final reports for UNC ACRs

Thank you for these reports, (b) (6) I will send responses soon. Feel free to call any time today before 2:00.
Axel Wolff

From: (b) (6)
Sent: Thursday, May 16, 2019 1:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6)
Subject: RE: Written final reports for UNC ACRs

Hello Dr. Wolff,
Attached you will find the final written reports for three verbally reported animal welfare concerns. These reports are now closed: 1-19-2, 2-19-1, and 2-19-2 (all verbally reported on 2/14/19). ACR 7-18-2, reported 7/23/18 is also closed and attached.

ACR 1-19-1, verbally reported to your office on 1/29/19, remains open, under IACUC review.

Please let me know when I can call to report another concern today. I tried several of you and got voicemails.

Thanks!

(b) (6)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, February 19, 2019 6:10 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Written final reports for UNC ACRs

Thank you for these reports, (b) (6) I will send responses soon.
Axel Wolff

From: (b) (6)

Sent: Monday, February 18, 2019 11:53 AM

To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b) (6)

Subject: Written final reports for UNC ACRs

Good Morning Dr. Wolff,

Attached you will find the final written reports for four verbally reported animal welfare concerns, dating back to October 2018.

In each report you will find the date that we verbally reported the concern to your office, should you need that to help reconcile your forms with our reports.

We appreciate your patience as we have several layers of University oversight to work through prior to completion of these reports. If you have any questions or require additional follow-up for any of these, please let us know.

I recently verbally reported 3 additional concerns: 1-19-1 (on 1/29/19), 1-19-2, 2-19-1, and 2-19-2 (on 2/14/19). Those are all still under IACUC review and will be sent to you as soon as they are completed.

Happy Monday –

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: *aw*

Date: 2/14/19

Time: 10:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of North Carolina - Chapel Hill

Assurance number: A 3410

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Pig died under anesthesia because pop up valve closed
Vet tried to salvage animal but it was euthanized*

Species involved: *Pig*

Personnel involved:

Dates and times:

Animal deaths: 1

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

reported to USDA

checklist

Projected submission to OLAW of final report from Institutional Official:

2-19-1

OFFICE USE ONLY

Case # _____