



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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

February 19, 2019

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

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 February 15, 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 January 10, 2019. According to the information provided, OLAW understands that one of two analgesics described in the protocol was not being used in a survival mouse procedure and the one being used had expired. Six mice and one rat received the expired analgesic.

The corrective actions consisted of maintaining a log of the expiration dates of all surgical drugs and ordering new surgery drugs three months prior to expiration. A procedure checklist will be used which lists use of the intra-operative analgesic.

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 institution 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

(b) (6)



## 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#: 12-18-1

NIH Grant #: N/A

Reported by: TCC

Recorded by: TCC

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

## Part I: Animal Concern Subcommittee (ACS) Report

1) **Concern & Summary of Events:** On December 5, 2018 the OACU TCC performed a semi-annual lab inspection and procedural observation with the PI. During the procedural observation, the PI explained that the lab did not utilize one of the two analgesics as described in the protocol for survival mouse procedures (intraoperative bupivacaine). The analgesic used (banamine) was past its expiration date (by one month) when used as the sole source of post-operative analgesia in six mice. Additionally, one rat received both bupivacaine and the expired banamine.

### 2) Principal Investigator (PI) Response:

The PI took responsibility for the incident and has started a log of the expiration dates of all surgical drugs, that will be attached to the surgery instrument box. Thus, the expiration dates will be validated before every procedure. Also, the PI implemented a process to order new surgery drugs three (3) months prior to the expiration date.

The PI has also implemented a procedural checklist that includes as a step the infiltration of the bupivacaine prior to the incision.

### 3) Findings of Fact, Conclusions, and ACS Recommendations:

#### a) Standards:

Failure to adhere to approved IACUC protocol  
Use of expired analgesic

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- b) **Findings of Fact:** Seven animals (six mice and one rat) were given an expired analgesic. Six mice did not receive intra-operative analgesia as described in approved protocol.
- c) **Subcommittee Recommendations:** OACU reported this incident to the ACS on 12/14/2018. The PI investigated the issue of expired banamine and lack of intra-operative analgesics in the mouse surgeries and provided proposed actions to be taken to prevent future occurrences.

All ACS members agreed that the PI's proposed actions were satisfactory and no sanctions were warranted. The ACS deemed these issues reportable to OLAW; therefore, the ACR process was initiated following the deficiency inspection report.

NIH funds were not used to support this project.

The subcommittee recommendations along with the PI's proposed actions were presented to the IACUC at the January 11, 2019 meeting.

4) **MOU, Subcontractors and/or DoD funding: Reporting required** ☐ Yes ☐ No ☒ NA

5) **Required Report to OLAW:** ☒ Yes ☐ No

If Yes: Verbally Reported to OLAW by: EW Date: 1/10/19 Time: 10:35am w/ AW

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## Part II: IACUC Conclusion and Report to Institutional Official

1) **IACUC Meeting Date and Closure:** The IACUC met on January 11, 2019 and voted to accept the ACS recommendations and close this ACR.

2) **Additional Requirement(s):** None

3) **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

**Terry Magnuson, Ph.D.**  
Institutional Official

  
Signature

2/15/19  
Date

CC:  
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]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, February 19, 2019 6:10 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.  
Axel Wolff

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**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: 1/10/19

Time: 10:30

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of North Carolina Chapel Hill

Assurance number: ~~A4372~~ A3410

Did incident involve PHS funded activity? NO

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Didn't use 1 of 2 analgesic, analgesic expired

Species involved: Mouse, Rat

Personnel involved:

Dates and times:

Animal deaths:

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

New drugs, check expiration dates, more documentation

Projected submission to OLAW of final report from Institutional Official:

12-18-1 VNC#

OFFICE USE ONLY

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