



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  
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Telephone: (301) 496-7163  
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February 19, 2019

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

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 rats received a non-pharmaceutical grade antibiotic. Also, two rats died unexpectedly and one required euthanasia.

The corrective actions consisted of amending the protocol to include a pharmaceutical grade version of the antibiotic and to reduce the dosage.

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#: 12-18-2

NIH Grant #: NA

Reported by: PI

Recorded by: EW/SQ

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

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

1) **Concern/Allegation:** During a pilot study, non-pharmaceutical/non-veterinary grade polymyxin B, included in the protocol narrative but not listed in applicable sections of the approved protocol, was used to treat animals. The PI also reported unexpected deaths of three rats: two died, and one was euthanized.

### 2) PI Self-Report & Summary of Events:

The PI self-reported the events to the IACUC and chose to stop the experiments to provide time to review the laboratory's procedures and understand the reason for the loss of these animals.

The PI rectified the absence of the mention of polymyxin B in the protocol by submitting a protocol amendment to the IACUC.

The PI also explained his process for choosing the non-pharmaceutical/non-veterinary grade polymyxin B based on available literature and confirmed the availability of pharmaceutical grade polymyxin B for future experiments. The PI communicated his plan to reduce the dosage in future experiments.

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

a) Standards: University Standard for Administered Agents: Utilization of scientific grade drugs when pharmaceutical or veterinary grade drugs are available.

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OFFICE OF ANIMAL CARE AND USE

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- b) Findings of Fact: Non-pharmaceutical/Non-Veterinary grade drugs were utilized in pilot study.
- c) Subcommittee Recommendations: OACU reported this incident to the ACS on 01/09/2019. The PI investigated the issue pertaining to use of a non-pharmaceutical/non-veterinary grade drug 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 the issue 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 01/11/2019 meeting.

- 4) **Required Report to OLAW:** ☒ Yes ☐ No  
If Yes: Verbally Reported to OLAW by: EW Date: 1/10/2019 Time: 1:45pm

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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)**:

- 3) **IACUC Vote**: Reportable ☒ Not Reportable ☐  
Unanimous ☒ Minority Opinion ☐  
Closed ☒ Pending ☐  
NIH Reimbursement Required ☐ Yes ☐ No ☒ NA

Terry Magnuson, Ph.D.  
Institutional Official

(b) (6)  
\_\_\_\_\_  
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

\*Pending response from PI, this sentence will be updated.

**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

**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: *1:45*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? *?*

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

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

What happened?

*2 rats died, 1 euthanized, used unapproved non-pharmaceutical drug.*Species involved: *Rats*

Personnel involved:

Dates and times:

Animal deaths: *3*

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

*Ordered proper drug, lowered dose, amended protocol*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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

*12-18-2 UNC#*