



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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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

December 20, 2019

Re: Animal Welfare Assurance  
#A3410-01 (OLAW Case 7E)  
Ref: ACR#: 10-19-1

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 December 18, 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 November 12, 2019. According to the information provided, OLAW understands that recently expired euthanasia solution was used in a terminal perfusion of one rat. There was no problem in the conduct of the procedure.

The corrective actions consisted of clearly labeling all drug bottles on the front and back with the expiration date, modifying the controlled drug log to include expiration dates, adding the expiration date to the online laboratory calendar, and putting red tape on expired drug bottles.

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  
Director of Animal Care and Use  
IACUC Training & Compliance Manager



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at CHAPEL HILL

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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](mailto: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#: 10-19-1

NIH Grant #: AA026537

Reported by: T&C

Recorded by: T&C

Verbal: ☒

Written: ☐

Complainant wishes to remain anonymous: ☐ Yes ☒ No

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

1) **Concern/Allegation:** Use of expired drugs as an anesthetic agent.

2) **Summary of Events:** During a routine semiannual inspection, drug logs indicated Fatal Plus was used past its expiration date on 9/13/19 as the anesthetic agent for a terminal perfusion in one rat.

3) **Principal Investigator (PI) Response:**

The PI acknowledged the error and implemented steps to prevent future occurrences:

1. The PI or LAC will clearly label the expiration date on the front and back of all new bottles.
2. The Controlled Substance Animal Use Log will be updated to include expiration date on the top of the sheets.
3. The PI will add the expiration date to the shared online lab calendar.
4. An expired bottle will be marked with red tape on the front, back, and lid.

4) **Findings of Fact, Conclusions, and ACS Recommendations:**

a) **Standards:**

OLAW FAQs Section F5

"The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The



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veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals."

Guide, page 122, indicates:

"Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely."

- b) Subcommittee Recommendations: OACU reported this incident to the ACS on October 29, 2019. The PI investigated the issue of CONCERN and provided proposed actions to be taken to prevent future occurrences.

All ACS members agreed that the PI's proposed actions were satisfactory, no sanctions were warranted, and that it should be reported to OLAW. NIH funds were used to support this project. The ACS determined that the costs involved in determining an accurate assessment of the reimbursement cost would exceed the cost of the experimental mice and thus determined that no reimbursement was necessary.

- 5) Required Report to OLAW: ☒ Yes ☐ No  
If Yes: Verbally Reported to OLAW by: MC Date: 11/12/19 Time: 8:15am  
6) Required Report to USDA: ☐ Yes ☒ No  
If Yes: Verbally Reported to USDA by: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

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

- 1) IACUC Meeting Date and Closure: The IACUC met on December 3, 2019 and voted to accept the ACS recommendations and voted to close the ACR.

- 2) Additional Requirement(s): N/A

- 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

12/18/19

Date

CC:

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

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, December 18, 2019 3:58 PM  
**To:** (b) (6) Wolff, Axel (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: ACR 10-19-1

Thank you for 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:** (b) (6)  
**Sent:** Wednesday, December 18, 2019 3:09 PM  
**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:** ACR 10-19-1

Dear Dr. Wolff,

The IACUC met on December 3, 2019 and reviewed Animal Concern 10-19-1. The IACUC voted unanimously to accept the subcommittee's recommendations and close this case. A copy of the Final report for this ACR is attached. Please let me know if you have any questions or concerns.

Thank you, and happy holidays.

(b) (6)

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Thursday, December 19, 2019 6:38 AM  
**To:** (b) (6)  
**Subject:** RE: ACR 10-19-1

Thanks (b) (6) I'll send a response soon.  
Axel Wolff

**From:** (b) (6)  
**Sent:** Wednesday, December 18, 2019 3:09 PM  
**To:** Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
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Thank you, and happy holidays.

(b) (6)

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(b) (6)



## Initial Report of Noncompliance

By: aw

Date: 11/12/19

Time: 8:15

Name of Person reporting: (b) (6)  
 Telephone #: (b) (6)  
 Fax #:  
 Email:

Name of Institution: U of North Carolina - Chapel Hill  
 Assurance number: A3410

Did incident involve PHS funded activity? yes  
 Funding component: \_\_\_\_\_  
 Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Recently Expired euthanasia solution used for a perfusion.  
No problems with procedure

Species involved: Rat

Personnel involved:

Dates and times:

Animal deaths:

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

Counsel staff

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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