



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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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

February 19, 2019

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

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 October 31, 2018. According to the information provided, OLAW understands that one mouse died and three required euthanasia after being subjected to retro-orbital bleeding which was not approved in the protocol. Also, the monitoring cards had been filled out in advance. The same investigator improperly euthanized mice with CO₂.

The corrective actions consisted of retraining the investigator, having the investigator work with a second person until all retraining has been completed, and allowing retro-orbital bleeding only on euthanized mice (or amend the protocol).

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#: 10-18-1

NIH Grant #: NA

Reported by: PI/DCM Veterinarian

Recorded by: EW

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

- 1) **Concern/Allegation/Summary:** A researcher performed the technique of retro-orbital bleeds on a group of mice when such technique was not described within the approved protocol. Several mice treated with this technique were found dead or required euthanasia. Additionally, the same researcher allegedly prematurely completed the purple cards used for monitoring of these animals making it impossible to correctly determine the actual time/frequency of monitoring.

Upon discovery of the animals at issue, DCM Vet Services alerted the research group, and advised, in two separate communications, that they report the unapproved activity to the IACUC. Although the laboratory member who performed the technique was certified to do so, the technique was not described in the approved protocol.

The researcher at issue was also involved in a separate instance of improperly euthanizing mice via CO2 in the animal facility. Although, the CO2 issue was initially handled by the OACU via email to the PI and LAC, it is deemed to be relevant to the overall conduct of the individual and was, therefore, included in the allegation notice for the PI to address.

The PI accepted full responsibility for the issues stated in the allegation notice related to the CO2 and for use of the unapproved technique. The PI acknowledged that the technique is not approved under the current protocol and, by way of explanation, noted that the technique was included on a previous protocol that had expired without the researcher realizing it.

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

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a) Standards:

IACUC Approved Protocol
University Standard for Mouse and Rat Euthanasia

- b) Findings of Fact: One mouse was found dead and three required euthanasia after retro-orbital bleeds were performed, inconsistent with the approved protocol. Additionally, the researcher inaccurately documented monitoring time on purple cards and, in an earlier incident, did not follow protocol for euthanasia via CO2.

- c) Subcommittee Recommendations: OACU reported this incident to the ACS on 10/24/2018. The PI investigated the following issues: performing a technique not described within an approved protocol; premature documentation of monitoring; and performing CO2 euthanasia in a manner not approved by the IACUC euthanasia standard. The PI provided proposed actions to be taken to prevent future occurrences.

All ACS members agreed that the PI's proposed actions were satisfactory and suggested retraining of the researcher on proper euthanasia technique and protocol compliance. Two ACS members indicated that the researcher involved should be required to work in the presence of a second lab member until retraining is completed.

NIH funds were not used to support this project. The subcommittee recommendations along with DCM's proposed actions will be presented to the IACUC at the November 2, 2018 meeting.

3) **MOU, Subcontractors and/or DoD funding:**

Reporting required ☐ Yes ☒ No ☐ NA

4) **Required Report to OLAW:**

☒ Yes ☐ No

If Yes: Verbally Reported to OLAW by: EW, Date: 10/31/2018, Time: 8:50am

Part II: IACUC Conclusion and Report to Institutional Official

- 1) **IACUC Meeting Date and Closure:** November 2, 2018. The IACUC accepted the ACS recommendations and required that the researcher named in this ACR receive the following re-training: hands-on retroorbital bleeding and CO2 euthanasia techniques and the online IACUC Orientation. The researcher was retrained by the TCM on 11/7/2018, and was advised to take the online IACUC Orientation as soon as possible.
- 2) **Additional Requirement(s):** The IACUC indicated that should further retroorbital bleeds be required for this or future studies, they must be conducted after euthanasia, or an amendment must be approved to include the technique in the PI's current protocol.

- 3) **IACUC Vote:** Reportable ☒ Not Reportable ☐

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THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

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OFFICE OF ANIMAL CARE AND USE

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F 919-966-8429
iacuc@med.unc.edu

Unanimous ☒ Minority Opinion ☐
Closed ☒ Pending ☐
NIH Reimbursement Required ☐ Yes ☐ No ☒ NA

(b) (6)

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]

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: 10/31/18

Time: 9:00

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

ref: 10-18-1

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?

Retro orbital bleeds performed, not on protocol, several mice died

Species involved: mice
Personnel involved: _____
Dates and times: _____
Animal deaths: _____

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

Retrain, work w second person

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY
Case # _____