



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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

January 31, 2020

Re: Animal Welfare Assurance
#A3410-01 (OLAW Case 7J)
Ref: ACR#: 12-19-1

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 January 23, 2020 letter reporting an adverse event involving guinea pigs at the University of North Carolina at Chapel Hill, following up on an initial telephone report on December 18, 2019. According to the information provided, OLAW understands that three guinea pigs sustained burn lesions on their backs from a dry heating pad used during surgery. The injury was only noticed several days after the procedure when the tissue thickened and scabbed. The project was supported by Veterans Affairs grant 5I01BX002282.

The corrective actions consisted of the veterinary staff treating the wounds and providing analgesia which resulted in full recovery. A water circulating heating pad with precise temperature controls will now be used to prevent burns.

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 on Humane Care and Use of Laboratory Animals.

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
Michael Fallon, D.V.M., Ph.D., VA Chief Veterinarian
(b) (6)
Robert Gibbens, D.V.M., USDA-APHIS-AC



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#: 12-19-1

NIH Grant #: VA 5I01BX002282

Reported by: NT (self-report)

Recorded by: T&C

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

1) Concern/Allegation: Unexpected post-surgical outcome

Summary of Self-Report: An LAC provided a self-report to the OACU on Monday, December 9, 2019 that three guinea pigs were found with similar lesions to their caudal dorsum - full-thickness circular lesions extending across the back that were partially granulated in. The veterinary staff anesthetized, clipped, cleaned, and debrided the wounds and treated the animals with Baytril, silver sulfadiazine cream, and a dose of buprenorphine. The veterinarian suspected the lesions were a result of a burn, likely from the heating pad used during surgery. The lesions may not have been apparent for several days until the tissue started to thicken and scab. The guinea pigs fully recovered. The lab has since switched to a water circulating heating pad with precise temperature controls to eliminate the possibility of contact burns.

2) Principal Investigator (PI) Response: This was a self-report.

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

- Standards:** The Guide states on page 119 that during postsurgical care "animals should be in a clean, dry, and comfortable area where they can be observed frequently by trained personnel. Particular attention should be given to thermoregulation..."
- Subcommittee Recommendations:** OACU reported this incident to the ACS on December 13, 2019. The PI and DCM veterinarians investigated the issue of CONCERN and provided proposed actions to be taken to prevent future occurrences. All ACS members agreed that the



PI's and DCM's proposed actions were satisfactory, no sanctions were warranted, and that it should be reported to OLAW. NIH funds were not used to support this project.

Additional Information received on January 9, 2020 from LAC

At the request of the Veterinary Medical Officer at the XX VAHCS, the LAC provided the following answers to their questions:

1. Exactly what apparatus were you using before switching to circulating water pad?
 - a. Regular dry heating pad.
2. Did the apparatus have a feedback mechanism to regulate temperature?
 - a. We monitored guinea pigs temperature rectally continuously throughout and adjusted the temperature of the heating pad accordingly if the animal was too warm or cold.
3. Approximately, how long are the animals on supplemental heat for surgery?
 - a. After induction of anesthesia until closure of the skin, generally 90-120 minutes.
4. How are the animals monitored while on the heating pad?
 - a. Monitored with vitals (respiratory rate/quality, mucous membranes, pulsatility of aorta, rectal temperature, pedal reflex, fullness of Inferior vena cava to help assess fluid status).
5. How are they monitored daily post-op?
 - a. Animals are monitored by the lab for three days following surgery, then three times per week. Animals are monitored for pain and distress, infection, return of bowel and bladder function, ischemia, graft patency, movement, and capillary refill on back legs for 3 days post op.
 - b. All animals are visually monitored for health and well-being at least once daily by DCM husbandry technicians, with any abnormalities reported to DCM Veterinary Services for examination by a veterinarian on the same day.
6. Was a biopsy done on the skin? If not, how do you know it was a "full thickness" lesion?
 - a. Full thickness skin lesions were visible to the veterinarian during a physical examination.
7. Were the remaining GPs checked for potential lesions or scarring?
 - a. Yes.

- 4) Required Report to OLAW: ☒ Yes ☐ No
If Yes: Verbally Reported to OLAW by: MC Date: 12/18/19 Time: 8:05am
- 5) Required Report to USDA: ☒ Yes ☐ No
If Yes: Verbally Reported to USDA by: TH Date: 12/12/19 Time: 8:15am

Part II: IACUC Conclusion and Report to Institutional Official

- 1) IACUC Meeting Date and Closure: The IACUC met on January 10, 2020 and voted to accept the ACS recommendations and close the ACR. A finalized report will be sent to the XX VAHCS.



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

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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

1/23/20
Date

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

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, January 31, 2020 6:33 AM
To: (b) (6)
Subject: RE: ACR 12-19-1

Thanks. I'll reply soon.
Axel Wolff

From: (b) (6)
Sent: Friday, January 24, 2020 1:06 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 12-19-1

Dear Dr. Wolff,

The IACUC met on January 10, 2020 and reviewed Animal Concern 12-19-1. 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.
(b) (6)

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(b) (6)



CO
VA
USDA
A3410-NJ

Initial Report of Noncompliance

By: and

Date: 12/18/19

Time: 8:15

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Univ North Carolina

Assurance number: A 3410

Did incident involve PHS funded activity? No - VA

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

3 guinea pigs had lesions following surgery due to bleeding
post

Species involved: Guinea Pigs

Personnel involved:

Dates and times:

Animal deaths:

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

Treated animals + recovered

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____