



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

May 17, 2019

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

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 May 14, 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 February 14, 2019. According to the information provided, OLAW understands that cardiac survival surgery was performed on zebrafish without oversight by a veterinarian as stipulated in a protocol amendment. The surgeon had not been certified by a veterinarian to perform surgery on live fish.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring a meeting of the Principal Investigator, veterinarian, an IACUC member, and the Training and Compliance Manager to explain the requirements for training of the surgeons.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC 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



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#: 1-19-2

NIH Grant #: NA

Reported by: DCM Veterinarian

Recorded by: TCM

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

- 1) **Concern/Allegation:** The PI submitted an amendment in July 2018, to remove analgesia from the post-operative care regimen for zebra fish that received cardiac apex resection survival surgery. As part of the amendment review process, the DCM Veterinary reviewer required that the surgical procedure be observed, and the fish be monitored post-operatively by a DCM veterinarian prior to approval of the amendment. IACUC representatives reviewed records in the months following, indicating that two surgeons had performed survival surgery on fish, without prior observation by the DCM Vet. The first incident was handled via Significant Deficiency comment in the Post Approval Monitoring report. In the second, discovered later, the issue was elevated to Animal Concern. The PI's responses indicated that they had been confused with proper procedure for this observation and subsequent approval process. During IACUC review of the case, at the March 8, 2019 meeting, the IACUC indicated that a face to face meeting shall be scheduled to ensure that the PI and the IACUC are completely clear on expectations going forward for surgical training with survival surgeons in the lab.

The face to face meeting, mentioned above, was held on March 28, 2019, and included the PI, a DCM Veterinarian, an IACUC Member familiar with the PI and the case, and the TCM. The group agreed upon a plan and a process going forward, and this information was provided to the PI via email on April 3, 2019.

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

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THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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

- a) Standards: (Cite regulation, standard, IACUC policy): Failure to comply with protocol approval requirement for additional training and certification.

Findings of Fact: Despite requirements for certification by a DCM veterinarian, an uncertified surgeon performed surgeries on live fish.

- b) Subcommittee Recommendations: OACU reported this incident to the ACS on February 7, 2019.

The subcommittee recommendations along with the PI's response was presented to the IACUC at the March 8, 2019 meeting.

- 3) Required Report to OLAW: ☒ Yes ☐ No
If Yes: Verbally Reported to OLAW by: TCM Date: 2/14/19 Time: 10am, to AW

Part II: IACUC Conclusion and Report to Institutional Official

- 1) IACUC Meeting Date and Closure: The IACUC met on March 8, 2019, reviewed the case and voted to close it with expectation that the face to face meeting would be scheduled with the PI as soon as possible.

- 2) 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

5/14/2019

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: Friday, May 17, 2019 6:45 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. Feel free to call any time today before 2:00.
Axel Wolff

From: (b) (6)
Sent: Thursday, May 16, 2019 1:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6)
Subject: RE: Written final reports for UNC ACRs

Hello Dr. Wolff,
Attached you will find the final written reports for three verbally reported animal welfare concerns. These reports are now closed: 1-19-2, 2-19-1, and 2-19-2 (all verbally reported on 2/14/19). ACR 7-18-2, reported 7/23/18 is also closed and attached.

ACR 1-19-1, verbally reported to your office on 1/29/19, remains open, under IACUC review.

Please let me know when I can call to report another concern today. I tried several of you and got voicemails.

Thanks!

(b) (6)

(b) (6)



From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, February 19, 2019 6:10 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
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: anDate: 2/14/19Time: 10:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of North Carolina - Chapel HillAssurance number: A3410Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Zelmafish surgery done without vet oversight as required by protocol

Species involved: Fish

Personnel involved:

Dates and times:

Animal deaths:

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

Vet will watch surgery

Projected submission to OLAW of final report from Institutional Official:

1-19-2

OFFICE USE ONLY

Case # _____