



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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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

May 17, 2019

Re: Animal Welfare Assurance
#A3410-01 (OLAW Case 7A)

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 a biology class was using fish in experiments and observing birds without an approved protocol in place and without adequate training. These activities had been conducted for several years with no Institutional Animal Care and Use Committee (IACUC) approval.

The corrective actions consisted of stopping all work with live vertebrate animals until protocols were in place. Protocols were submitted to the IACUC to cover the fish and birds and a memorandum was sent to all Deans, Directors, Department Heads, Principal Investigators (PI), and Laboratory Animal Coordinators stating that a protocol was required for all live vertebrate animal activities, including teaching. A veterinarian counseled the PI on the husbandry of the animals and documentation. Training and Compliance staff will inspect the area semiannually.

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 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#: 2-19-2

NIH Grant #: NA

Reported by: Student

Recorded by: TCM

Verbal: ☐

Written: ☒

Complainant wishes to remain anonymous: ☐ Yes ☒ No

Part I: Animal Concern Subcommittee (ACS) Report

- 1) **Concern/Allegation/Summary of Events:** On February 7, 2019 the OACU received an email regarding animals used in [a biology lab] class this semester. It was reported that the class was performing experiments on live zebrafish and neon tetra fish without adequate training or IACUC approval. Upon further review of the syllabus, songbirds may be observed as well. The PI has since submitted two IACUC protocols to cover the fish and bird work. In the PI's responses to the concern, the PI indicated that he/she was unaware of the requirement for an IACUC protocol for the observational type of animal work being conducted in this class, and that due to a misunderstanding. Through conversations with the PI, the OACU learned that the use of animals has occurred in prior years of this course. The PI voluntarily stopped use of all vertebrates in the class until the IACUC protocols covering the work were approved.
- 2) **Findings of Fact, Conclusions, and ACS Recommendations:**
 - a) **Standards:** (Cite regulation, standard, IACUC policy): Per the PHS Policy on Humane Care and Use of Laboratory Animals "Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals."

"Live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes must be covered under an IACUC approved protocol."

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- b) **Findings of Fact:** Animals (fish and birds) have been observed as part of a biology laboratory for many years without being covered under an IACUC protocol.
- c) **Subcommittee Recommendations:** OACU reported this incident to the ACS on 2/13/2019. The ACS members agreed that the PI's explanation and proposed actions were satisfactory as the instructor indicated s/he was unaware of the protocol requirement for teaching purposes based on internal University conversations from over a decade ago. Some members questioned whether the instructor would have been aware of the requirement for a protocol for fish/bird undergraduate teaching prior to this allegation. The Vice Chancellor for Research had sent a memo in March 2018 to Department Chairs, Deans and Directors requesting information about the use of higher order invertebrates (such as cephalopods and lobsters). However, the memo did not contain information regarding the use of vertebrate animals for teaching purposes. At the time the memo was sent, the PI's Department Chair opted out of mass mailings and, therefore, may not have received it.

As a result of this concern, a subsequent memo was sent to Deans, Directors, and Department heads, current PIs, as well as their LACs and official contacts, and all University faculty to explain the requirement for IACUC protocols covering any live vertebrate animal work, including maintained for teaching purposes. The IACUC shall discuss the maintenance of these fish and whether a full satellite facility should be required during the next IACUC meeting.

The ACS members felt that no sanctions were warranted.

NIH funds were not used to support this work.

The subcommittee recommendations along with the PI's explanation and proposed actions 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: 2/14/2019 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 and accepted the ACS recommendations. The IACUC indicated that, due to the nature of the enclosure and the additional burden of creating and maintaining a satellite facility, a modified plan for oversight may be utilized for the tank(s) of fish maintained by this PI for the purpose of undergraduate courses. The T&C and a DCM Veterinarian will inspect the current location and discuss current feeding and water quality practices. Together with the PI, the group will create a documentation system to ensure ongoing adequate care of the fish maintained in the classroom. The space will be inspected by T&C semiannually, to ensure that documentation and housing conditions are adequately maintained.



THE UNIVERSITY
of NORTH CAROLINA
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

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: *clw*Date: *2/14/19*Time: *10:00*

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? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Biology behavior lab conducted for years without protocol. Fish + birds used*Species involved: *Neontetra fish, birds*

Personnel involved:

Dates and times:

Animal deaths:

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

Protocol submitted

Projected submission to OLAW of final report from Institutional Official:

2/19-2

OFFICE USE ONLY

Case # _____