

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

February 3, 2020

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

Re: Animal Welfare Assurance #A3410-01 (OLAW Case 7H) Ref: ACR#: 11-19-3

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 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 December 4, 2019. According to the information provided, OLAW understands that mice over 21 days of age were being toe clipped by an individual not approved to perform the procedure. The protocol did not include the procedure and institutional policy states that toe clipping is only approved up to 10 days of age.

The corrective actions consisted of counseling the individual responsible and removing the person from the project and from working with mice. All mice under this protocol have been euthanized and the Principal Investigator is in the process of leaving the institution.

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 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



Acronyms:

Principal Investigator (PI)

Division of Comparative Medicine (DCM)

UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Training and Compliance Coordinator (TCC)

Training and Compliance Team (T&C) Training and Compliance Manager (TCM)

OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569 CAMPUS BOX 7193 CHAPEL HILL, NC 27599-7115

F 919-966-8429 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.

Office of Animal Care Laboratory Animal C		Animal Concern Sub	committee (ACS)	
ACR#:	11-19-3	NIH Grant #: NA		
Reported by:	ECB	Recorded I	Recorded by: T&C	
Verbal:		Written:	\boxtimes	
Complainant wish	nes to remain anonymous:	☐ Yes	⊠ No	

Part I: Animal Concern Subcommittee (ACS) Report

1) Concern/Allegation: Toe clipping mice without approval and violating University Standard on Rodent Identification.

Summary of Events: On November 18, 2019, a DCM technician reported witnessing a researcher, YX, toe clipping "fully furred...at least 21 days old mice." In addition, the approved protocols for this investigator did not include the toe clip procedure and the individual, YX, is not approved to perform this procedure.

Principal Investigator (PI) Response:

The PI did not respond to multiple emails. On November 25, 2019, the co-PI on the protocol forwarded the OACU Director an email written by YX which responded to the allegation.

Due to the lack of oversight by the PI or co-PI, the PI's departmental administrative Chair has approved the budget and account number for all of this PI's breeding work to move to the DCM Colony Management group.

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

Standards:

The University Standard on Rodent Identification states that "Toe clipping must be scientifically justified in an approved IACUC protocol." In addition, "Toe clips must be performed on or before 10 days of age. The ideal timing is between 5-7 days of age when the toes are separate and the



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bone not calcified and the toes are no longer webbed. Toe clipping beyond 10 days of age is considered painful and is not an acceptable procedure for either identification or genotyping."

Subcommittee Recommendations: OACU reported this incident to the ACS on November 26, 2019. The PI/DCM investigated the issue of CONCERN and provided proposed actions to be taken to prevent future occurrences.

The majority of ACS members agreed that the co-PI's response was inadequate. They also agreed that no sanctions were warranted and that it should be reported to OLAW. NIH funds were not used to support this project.

Additional Information from PI's Department after ACS deliberation:

The individual who clipped the toes inappropriately was reminded of the University Standard, and that s/he would no longer have any responsibility for this project nor should have any direct involvement with the care of the mice.

Additional Information received on December 3, 2019 from Pl's Department

The PI, whose work at the institution was coming to a close, discussed the situation with departmental administration and it was determined that all mice associated with the protocols should be euthanized. The lab manager euthanized all the mice in the PI's colonies in all facilities. There are no longer any mice covered under the PI's protocols.

3)	Required Repo	ort to OLAW: y Reported to OLA	⊠ Yes W by:MC	☐ No Date:1	2/4/19 Tim	ne: _9am	
4)	Required Repo	ort to USDA: y Reported to USD	☐ Yes A by:	⊠ No Date:	Ti	me:	
Pa	art II: IACI	UC Conclusion a	and Report to In	stitutional (Official		6
1)		g Date and Closure ndations and close t		on January 10,	2020 and vo	ted to accept th	е
2)	Additional Rec	quirement(s): N/A					
3)	IACUC Vote:	Reportable 🖂 Unanimous 🖂 Closed 🖂 NIH Reimbursem	Not Reportable Minority Opinio Pending ent Required	n 🔲 🗎 🗎 Yes	□ No	⊠ NA	



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(b) (6)

Terry Magnuson, Ph.D. Institutional Official

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 6:31 AM

To:

(b) (6)

Subject:

RE: ACR 11-19-3

Thanks. I'll reply soon.

Axel Wolff

From:

(b) (6)

Sent: Friday, January 24, 2020 12:43 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 11-19-3

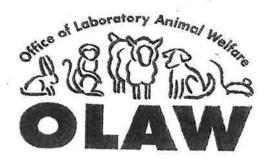
Dear Dr. Wolff,

The IACUC met on January 10, 2020 and reviewed Animal Concern 11-19-3. 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.

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(b) (6)



Initial Report of Noncompliance

Ву: (b) (6)

Date: 12/4/19	Time: 9	.00
Name of Person reporting: Telephone #: Fax #: Email:	(b) (6) (b) (6)	
Name of Institution: Assurance number:	13410 Verth Carolina -	Charled Hiel
Did incident involve PHS for Funding component: Was funding component c		
What happened? Muce tree Clayeres	t ever 10 days of. Stie	lent not approved,
Species involved: Mr ce Personnel involved: Dates and times: Animal deaths:		
Projected plan and schedule	for corréction/prevention (if know	vn):
	ermie, lab shit do	
Projected submission to OLA	AW of final report from Institution	nal Official:
OFFICE USE ONLY Case #		