



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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Bethesda, Maryland 20892-7982  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

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Rockledge One, Suite 360  
6705 Rockledge Drive  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

August 21, 2020

Re: Animal Welfare Assurance  
#A3410-01 (OLAW Case 7L)  
Ref: ACR#: 6-20-2

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 August 10, 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 July 16, 2020. According to the information provided, OLAW understands that several mice were subjected to surgical procedures which were not included in the approved protocol. The procedures had been described in a protocol which had expired and the Principal Investigator (PI) assumed the information did not need to be described in the current protocol.

The corrective actions consisted of counseling the PI on the protocol process. The PI will now have the laboratory staff discuss all proposed animal activities during laboratory meetings to prevent a recurrence.

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



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

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### Confidential Letter

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

Date: August 10, 2020

|              |   |
|--------------|---|
| Institution: | University of North Carolina at Chapel Hill |
| Assurance #: | D16-00256 (A 3410-01)                       |
| NIH Grant #: | R01NS102412                                 |
| Case #:      | 6-20-2                                      |

Dear Dr. Wolff:

Please find notice of the Institutional Animal Care and Use Committee's (IACUC) investigation and report of a recent animal welfare concern.

On June 29, 2020, the IACUC was notified of mice that had undergone surgical procedures that were not in an active, approved protocol. The Principal Investigator (PI) explained that the procedure was in an expired protocol and erroneously believed it did not need to be included in its continuation. The process was explained to the PI, who also implemented a policy that all proposed experiments will need to be presented and approved at laboratory meetings to avoid future incidents.

After gathering information and informing the Animal Concern Subcommittee (ACS), the Office of Animal Care and Use (OACU) staff verbally reported this incident to OLAW on July 16, 2020.

The IACUC met to discuss the case on August 7, 2020. The IACUC voted unanimously to close the ACR after accepting the ACS recommendations that no additional actions were required, no sanctions were warranted, and a report should be made to OLAW. NIH funds were used to support this project. The IACUC determined that no reimbursement was necessary.

Please let me know if you have any additional questions regarding this investigation.

Sincerely,

(b) (6)

Terry Magnuson, Ph.D.  
Vice Chancellor for Research and Institutional Official

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, August 19, 2020 7:21 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: ACR 6-20-2

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

**From:** (b) (6)  
**Sent:** Tuesday, August 18, 2020 12:09 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 6-20-2

Dear Dr. Wolff,

The IACUC met on August 7, 2020 and reviewed Animal Concern 6-20-2. 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)

(b) (6)



## Initial Report of Noncompliance

By: (b) (6)

Date: 7/16/20

Time: 8:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of North Carolina - Chapel Hill

Assurance number: A3410

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*Cranial injections done on 10-12 mice but not as protocol. PI misunderstood language in protocol system, mice ok*

Species involved: *Mouse*

Personnel involved:

Dates and times:

Animal deaths:

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

*Amend protocol*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_