



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 - MSC 7982
Bethesda, Maryland 20892-7982
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

February 10, 2017

Re: Animal Welfare Assurance
A3145-01 [OLAW Case 1Y]

Dr. Mark Chance
Vice Dean for Research
Case Western Reserve University
School of Medicine
10900 Euclid Avenue
Cleveland, OH 44106-4988

Dear Dr. Chance,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 31, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Case Western Reserve University, following up on an initial report on September 30, 2016. According to the information provided, OLAW understands that five cages of 4-5 week old mice were subjected to tail snips without anesthesia/analgesia and without adequate documentation. The procedure was not included in the approved protocol and was performed by a laboratory member not listed on the protocol.

The corrective actions consisted of requiring the Principal Investigator (PI) and staff to read and certify understanding of the protocol, to take the new Genotyping Class, and to have the PI submit a corrective action plan to the Institutional Animal Care and Use Committee stating that procedures will be performed as described in the approved protocol. The protocol was amended to add the laboratory member.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair



SCHOOL OF MEDICINE
CASE WESTERN RESERVE
UNIVERSITY

Mark R. Chance, Ph.D.
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January 31, 2017

Axel V. Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL I, Suite 360, MS 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

cc: Brent Morse, DVM

Re: Assurance# A3145-01

Dear Dr. Wolf,

The purpose of this letter is to report the final findings of a noncompliance investigation reported to your office by letter dated September 30, 2016 and the institutional actions that have been and will be taken. The incident involved tail snips performed on five cages of mice between 4-5 weeks of age without the use of anesthesia, analgesia, or appropriate documentation. The tail snip procedure was not listed on the protocol. The procedure was performed by one lab member not listed on the protocol. These actions are inconsistent with IACUC guidelines and/or policies and the Guide for the Care and Use of Laboratory Animals.

The matter was reported to the IACUC Chair. The IACUC Chair appointed a subcommittee consisting of a scientist, a non-scientist, and a staff veterinarian to investigate the allegations. The subcommittee convened and investigated the matter.

The subcommittee presented its report to the IACUC on December 20, 2016. The IACUC concluded by majority vote that there were acts of serious non-compliance with animal care and use requirements with respect to performing unapproved procedures without proper anesthesia, analgesia.

The IACUC concluded by majority vote on the following recommended actions for the PI:

1. The PI and laboratory members must review all IACUC protocol(s) in which they are listed in order to identify and correct any other potential inconsistencies between approved procedures and laboratory practice. The PI must send an email to the PAM coordinator assuring that "The PI and all lab members have read and understand their respective protocol(s)."

2. All lab members are required to attend the new Genotyping Class. The PI will be contacted by Veterinary Services to schedule.
3. PI will provide the IACUC with a formal written plan to improve colony management, for discussion and approval at the convened meeting, in February 2017. The plan for future colony management should include a statement on the importance of following procedures listed in approved IACUC protocols and potential consequences of deviations from the approved methodology.
4. Amend protocol 2015-0039 to add the lab member referenced in this report.

All above recommendations are to be completed within 60 days from the PI's receipt of my formal letter dated January 18, 2017, unless otherwise noted.

A review of the billing records showed that all direct costs associated with the care and use of the mice during the time frame of this incident were paid from NIH Grant R01EY022937.

Programmatically, the IACUC and Animal Resource Center continuously review the training program for investigators and research staff as well as our written guidelines and policies, making adjustments where needed to strengthen the program. New genotyping guidelines have been established, which model the NIH OACU guidelines for the genotyping of mice and rats. These guidelines enhance our recently added Genotyping Class.

In closing, I want to assure you and your office of Case Western Reserve University's commitment to animal welfare regulations. Please let me know if you have any questions.

Sincerely,

(b) (6)



Mark Chance, Ph.D.
Vice Dean for Research
CWRU SOM IACUC Institutional Official
Charles W. and Iona A. Mathias Professor of Cancer Research
Director, Case Center for Proteomics and Bioinformatics

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 01, 2017 7:16 AM
To: (b) (6)
Subject: RE: Noncompliance Investigation CWRU Final Report (2016-11_JL)

Thank you for this letter (b) (6). We will respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: (b) (6)
Sent: Tuesday, January 31, 2017 2:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mark Chance <mrc16@case.edu>
Subject: Noncompliance Investigation CWRU Final Report (2016-11_JL)

Drs. Wolff and Morse,

Please find the attached final report from Dr. Mark Chance, the Institutional Official for Case Western Reserve University regarding a noncompliance investigation first brought to your attention on September 30th, 2016. Please do not hesitate to let us know if you have any further questions regarding this matter.

Thank you,

(b) (6)



A3145-1X



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September 30, 2016

Assurance No. A3145-01

Dear Dr. Wolff,

I am writing to inform you of an incident of alleged noncompliance discovered on July 18, 2016. The allegations involved tail snips performed on five cages of mice between 4-5 weeks of age without the use of anesthesia, analgesia, or appropriate documentation. The tail snip procedure was not listed on the protocol. The procedure was performed by one lab member not listed on the protocol. The mice were evaluated by Veterinary Services and found to be bright, alert, and responsive. The IACUC has formed a subcommittee to investigate this incident. This project is supported 100% by federal funds. We will report findings of our investigation to you upon completion of the investigation.

If you have questions, please advise.

Sincerely,

(b) (6)

Mark Chance, Ph.D.
Vice Dean for Research
CWRU SOM IACUC Institutional Official
Charles W. and Iona A. Mathias Professor of Cancer Research
Director, Case Center for Proteomics and Bioinformatics