



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 4027065

August 15, 2018

Re: Animal Welfare Assurance
A3145-01 [OLAW Case 2A]

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 August 10, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Case Western Reserve University. Your final report supplements information in your initial report made via a May 18th email attachment. According to the information provided, OLAW understands that on May 1, 2018 four mouse cages containing 12 mice were found housed in a laboratory without IACUC permission. The mice were in good condition. Two cages were returned to the animal facility and two were euthanized for tissue collection. A subsequent investigation confirmed that there was serious noncompliance. This activity was not PHS funded.

Corrective actions included having the PI submit a plan to the IACUC regarding the removal of animals from the Animal Facility to other locations for experimental procedures.

OLAW appreciates the prompt consideration of this matter by Case Western Reserve University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



SCHOOL OF MEDICINE
CASE WESTERN RESERVE
UNIVERSITY

Mark R. Chance, Ph.D.
Vice Dean for Research

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10900 Euclid Avenue
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Phone 216.368.0291
Fax 216.368.3812
mark.chance@case.edu

August 10, 2018

Brent Morse, 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

Re: Assurance# A3145-01

Dear Dr. Morse,

The purpose of this letter is to report the final findings of a noncompliance investigation reported to your office by letter dated May 18, 2018 and the institutional actions that have been and will be taken. The incident involved inappropriate laboratory housing of 4 cages of mice, 12 mice in total. The cages were under the care of two staff members, covered under two protocols belonging to the same Primary Investigator. The mice were identified by a Facility Services staff member. The mice had food, water, and were found to be in good condition. Two cages of mice were returned to the animal facility (ARC) by two ARC staff members and two cages of mice were euthanized for tissue collection. The actions of the lab members in regard to the inappropriate housing of these mice 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 June 19, 2018. The IACUC concluded by majority vote that there were acts of serious non-compliance with animal care and use requirements with respect to inappropriate housing of mice. The IACUC concluded by majority vote on the following recommended actions for the PI's animal research:

The PI should submit a plan to the IACUC regarding the removal of animals from the Animal Facility to other locations for experimental procedures on their approved protocols. Specifically, this plan should include the individuals that will be removing

the animals and the maximum amount of time that they will be outside of the facility. This plan should be communicated to all lab members and reviewed annually along with the IACUC protocol to ensure that the welfare of the animals is a priority.

The above recommendations are to be completed within 60 days from the PI's receipt of my formal letter dated July 26, 2018.

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 a nonfederal source.

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.

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)

A large rectangular area of the document is redacted with a solid grey box, obscuring the signature and any handwritten notes.

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: Friday, August 10, 2018 9:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance Investigation CWRU Final Report (2018_02_LM)

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

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, August 10, 2018 9:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mark Chance <mark.chance@case.edu>
Subject: Noncompliance Investigation CWRU Final Report (2018_02_LM)

Dr. 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 May 18th, 2018. Please do not hesitate to let us know if you have any further questions regarding this matter.

Thank you,

(b) (6)





SCHOOL OF MEDICINE
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Mark R. Chance, Ph.D.
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mark.chance@case.edu

May 18, 2018

Assurance No. A3145-01

Dear Dr. Wolff,

I am writing to inform you of an incident of alleged noncompliance discovered on May 1, 2018. The allegations involved unapproved and inappropriate laboratory housing of 4 cages of mice, 12 mice in total. The cages were under the care of two staff members, covered under two protocols belonging to the same Primary Investigator. The mice were identified by a Facility Services staff member. The mice had food, water, and were found to be in good condition. Two cages of mice were returned to the animal facility (ARC) by two ARC staff members and two cages of mice were euthanized for tissue collection. The IACUC has formed a subcommittee to investigate this incident. This project is supported 100% by nonfederal 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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 21, 2018 8:00 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Mark Chance
Subject: RE: New Noncompliance Investigation - CWRU Preliminary Report - 2018_02_LM

Thank you for sending this prompt preliminary report. We will open a case file and await further information.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Friday, May 18, 2018 3:54 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mark Chance <mark.chance@case.edu>
Subject: New Noncompliance Investigation - CWRU Preliminary Report - 2018_02_LM

Dear Dr. Wolff,

Please find the attached letter from Dr. Mark Chance, the Institutional Official for Case Western Reserve University, regarding a new IACUC noncompliance investigation we have begun.

Thank you,

(b) (6)

