



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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) 402-7065

December 4, 2019

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

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 November 25, 2019 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Case Western Reserve University, School of Medicine. According to the information provided, OLAW understands that on August 1, 2019, an incident of inappropriate housing of pre-weanling mouse pups of varying ages occurred. A husbandry technician employed by CWRU Animal Resource Center identified a total of 80 mice were present in one cage, 65 found dead and 15 found alive (note: the remaining 15 pups were immediately euthanized per CWRU SOP). It was determined that the cages were under the care of one staff member employed by the Athymic Animal Core. The matter was reported to the IACUC chair and a subcommittee was formed to investigate the allegations. A report from the subcommittee was presented to the IACUC on September 17, 2019. The IACUC concluded that there were acts of serious non-compliance with the animal care and use requirements with respect to inappropriate housing, weaning and care of mice. The following recommended actions were concluded by majority vote of the IACUC:

- Recommend the individual responsible be permanently prohibited from working with animals at CWRU or its affiliated institutions.
- Recommend that the Animal Resource Center educate those who work with research animals on compassion fatigue.
- Recommend that the Athymic Animal Facility employ a qualified, full-time manager to oversee the day-to-day operations of the core, with direct supervisory authority over the staff, and direct reporting to the Athymic Animal Facility Director. Also, recommend that the Athymic Animal Facility Director be the PI of the Athymic Animal Facility IACUC protocol.
- Recommend that the Athymic Animal Facility Director report on progress toward fulfilling IACUC recommendations at an IACUC meeting in six months.
- Recommend that the IACUC conduct periodic, unannounced inspections of the Athymic Animal Facility in the coming year.

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Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance.

We appreciate being notified of these matters and find no cause for further actions.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



SCHOOL OF MEDICINE
CASE WESTERN RESERVE
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November 25, 2019

Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Re: Assurance# A3145-01

Dear Dr. Wolff,

The purpose of this letter is to report the final findings of a noncompliance investigation reported to your office by letter dated August 1, 2019 and the institutional actions that have been and will be taken. The incident involved inappropriate housing of pre-weaning mouse pups of varying ages. There were a total of 80 mice in the cage – 65 dead and 15 still alive. There were no adult lactating females in the cage. The 15 live mice were immediately euthanized according to our standard procedure. The mice were identified by a husbandry technician employed by the CWRU Animal Resource Center. The cages were under the care of one staff member employed by the Athymic Animal Core. At the time of the incident, facility access was suspended for this employee. The actions of this staff member in regard to the inappropriate housing, weaning and care 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 September 17, 2019. 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, weaning, and care of the mice. The IACUC concluded by majority vote on the following recommended actions:

1. We recommend that individual responsible be permanently prohibited from working with animals at CWRU or its affiliated institutions.

2. We recommend that the Animal Resource Center educate those who work with research animals on compassion fatigue.
3. We recommend that the Athymic Animal Facility employ a qualified, full-time manager to oversee the day-to-day operations of the core, with direct supervisory authority over the staff, and directly reporting to the Athymic Animal Facility Director. We also recommend that the Athymic Animal Facility Director be the PI of the Athymic Animal Facility IACUC protocol.
4. We recommend that the Athymic Animal Facility Director report on progress toward fulfilling IACUC recommendations at an IACUC meeting in six months.
5. We recommend that the IACUC conduct periodic, unannounced inspections of the Athymic Animal Facility in the coming year.

I have accepted these recommendations and notified the PIs by letter dated October 1, 2019. Regarding recommended action #1, please be advised that the responsible individual no longer is employed at this institution. The remaining recommendations are to be completed within 6 months from the date of my letter to the PIs and the ARC/IACUC Post Approval Monitoring Committee will be following up to assess completion of these requirements.

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 both federal NCI Grant P30CA043703-29 (5%) and nonfederal sources (95%). The CWRU Office of Research Administration has removed the unauthorized costs from the federal grant. The NIH funding component has been notified of the situation.

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. The staff has already developed a plan for the implementation of compassion fatigue training for staff and researchers (IACUC recommended action #2). The IACUC received education in compassion fatigue at their Annual Retreat this month on October 15, 2019.

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 26, 2019 3:57 PM
To: Tami McCourt; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Mark Chance
Subject: RE: Noncompliance Investigation CWRU Final Report (2019_01_AAF)

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Tami McCourt [mailto:txm9@cwru.edu]
Sent: Monday, November 25, 2019 2:42 PM
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 (2019_01_AAF)

Dr. Wolff,

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 August 1st, 2019. Please do not hesitate to let us know if you have any further questions regarding this matter.

Thank you,

Tami McCourt RVT, BTAS, CMAR, CPIA

Director, Research Compliance IACUC

SOM ORA, IACUC

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tami.mccourt@case.edu

<https://case.edu/medicine/research/research-support/iacuc/iacuc-training>



SCHOOL OF MEDICINE
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August 1, 2019

Assurance No. A3145-01

Dear Dr. Wolff,

I am writing to inform you of an incident of alleged noncompliance discovered on July 9, 2019. The allegations involved inappropriate housing of preweaning mouse pups of varying ages. There were a total of 80 mice in the cage – 65 dead and 15 still alive. There were no adult lactating females in the cage. The 15 live mice were immediately euthanized according to our standard procedure. The cages were under the care of one staff member employed by the Athymic Animal Core. Facility access has been suspended for this employee pending the investigation and she is no longer caring for animals. The mice were identified by a husbandry technician employed by the CWRU Animal Resource Center. The IACUC has formed a subcommittee to investigate this incident. This project is supported 100% by federal funds. We will report the 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

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 5, 2019 9:51 AM
To: 'Tami McCourt'
Subject: RE: New Noncompliance Investigation - CWRU Preliminary Report - 2019_01_AAF

Thank you for this preliminary report. We will wait for your final response after your investigation is complete.

Regards,
Joan

From: Tami McCourt <txm9@cwru.edu>
Sent: Thursday, August 1, 2019 4:34 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 - 2019_01_AAF

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,

Tami McCourt RVT, BTAS, CMAR, CPIA

Director, Research Compliance IACUC

SOM ORA, IACUC

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(b) (6)

tami.mccourt@case.edu

<https://case.edu/medicine/research/research-support/iacuc/iacuc-training>