



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 22, 2018

Re: Animal Welfare Assurance  
#A3047-01 (OLAW Case 2L)

Serpil C. Erzurum, M.D.  
Chair, Cleveland Clinic Lerner Research Institute  
Lerner Research Institute  
Cleveland Clinic Foundation  
9500 Euclid Avenue, NB21  
Cleveland, OH 44195

Dear Dr. Ezurum,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Cleveland Clinic. According to the information provided, OLAW understands that two laboratory personnel performed unauthorized tail clip procedures on sixteen unanesthetized mice without prior IACUC approval and contrary to the institution's genotyping policy. It was identified during the noncompliance investigation that anesthetics were unavailable in the laboratory. The associated animal activities were supported by PHS funds.

The corrective actions consisted of immediately revoking both laboratory personnel's animal use privileges and access to the facility, reviewing the protocols and SOPs with the associates, retraining and educating both staff members, purchasing the appropriate anesthetics for the laboratory and the responsible individuals re-reading and re-signing the Certificate of Understanding.

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)

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair



Serpil C. Erzurum, M.D.  
Chair  
Lerner Research Institute

February 14, 2018

Brent C. Morse, D.V.M.  
Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20817

The Cleveland Clinic Institutional Animal Care and Use Committee (IACUC) concluded that animal research noncompliance occurred in the Cleveland Clinic Animal Care Program. Two individuals were observed by BRU personnel performing a tail clipping procedure on 16 mice that was not approved on their protocol and does not conform to our genotyping policy. These individuals did not use general anesthesia, as required. Access to the BRU and animal work were immediately revoked. During the course of the noncompliance investigation, it was determined that they did not have those anesthetic agents available in the lab. When informed about the incident by the IACUC, the PI met with these individuals to review protocols and SOPs. Appropriate anesthetics were purchased. The two lab members re-read the protocol and re-signed the Certification of Understanding. The BRU Education Specialist and IACUC Compliance Specialist met with these individuals for retraining and education. During this retraining, there was concern that one of the individuals lacked English proficiency to the extent that it was questionable if she understood the education and re-training session.

These facts were discussed at a convened meeting of the IACUC, at which time, the IACUC agreed with the actions to date. To address the English proficiency situation, two members of the IACUC volunteered to meet with each of these lab members individually to assess English comprehension. After these interviews were completed, the IACUC members reported to the IACUC that the lab members showed sufficient understanding of English language. Access to the animal facility and permission to perform animal work were restored.

The Animal Welfare Assurance number for Cleveland Clinic PHS-funded grants is A3047-01. This protocol is funded by PHS grants R01CA163881, R01CA138398 and 1K99CA190910-01.

Sincerely,

(b) (6)

Serpil C. Erzurum, (M.D.)  
Alfred Lerner Memorial Chair in Innovative Biomedical Research  
Chair, Cleveland Clinic Lerner Research Institute

SCE/ag

Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, February 15, 2018 8:58 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Cleveland Clinic Noncompliance Report - 2/14/2018 (2 of 2)

Thank you for this report. We will send a response soon.  
Axel Wolff

**From:** (b) (6)@ccf.org]  
**Sent:** Wednesday, February 14, 2018 3:49 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** accredit@AAALAC.org; (b) (6)@ccf.org>  
**Subject:** Cleveland Clinic Noncompliance Report - 2/14/2018 (2 of 2)

Dear Dr. Morse:

Attached please find a noncompliance report from the Subcommittee for Non-compliance of the Cleveland Clinic IACUC, dated February 14, 2018 (2 of 2).

Please acknowledge receipt.

Thank you,

(b) (6)



(b) (6)

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