



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) 402-7065

October 29, 2018

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

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. Erzurum,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 19, 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 a research associate performed unauthorized tail snip procedures in adult mice for genotyping without prior IACUC approval.

The corrective actions consisted of revoking the responsible individual's animal use privileges and advising the Principal Investigator to amend the protocol to include a method for genotyping adult mice. The IACUC also determined that data generated from the unapproved animal activities cannot be used and although the associated animal activities were PHS funded, all expenditures incurred during the period of noncompliance will be excluded from the applicable NIH grant.

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

October 19, 2018

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

Dear Dr. Morse:

The Cleveland Clinic Institutional Animal Care and Use Committee (IACUC) concluded that animal research non-compliance occurred in the Cleveland Clinic Animal Care Program. The incident occurred when a member of a research team collected tail snips from adult mice, while that procedure for tissue collection was not part of the approved IACUC protocol. The individual involved has been removed from working with live animals by the PI.

The IACUC reviewed this incident at the October 16, 2018 meeting and determined that this was reportable research non-compliance. At that meeting the IACUC also determined that data derived from animals that underwent this unapproved procedure could not be used, and advised the PI that cage charges related to these mice may not be charged to a Federal grant award. The IACUC also advised the PI to amend the IACUC protocol to include a method for tissue collection for the purpose of genotyping adult mice.

The laboratory involved is supported by 1R01CA222294-01A1 which has a title that matches that of an active protocol that was not involved in this incident. The Animal Welfare Assurance number for Cleveland Clinic is A3047-01.

Sincerely,

(b) (6)

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

SCE/ag

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