

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

June 5, 2018

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

Re: Animal Welfare Assurance A3047-01 [OLAW Case 2N]

Serpil C. Erzurum, M.D. Institutional Official Cleveland Clinic Lerner Research Institute 9500 Euclid Avenue, MC NB21 Cleveland, OH 44195

Dear Dr. Erzurum,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 1, 2018 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Cleveland Clinic. According to the information provided it is understood that a member of a research team euthanized a mouse that was assigned to a protocol on which the individual was not approved to work. The individual had been advised by the PI that animal procedures could not be conducted until approval of a pending amendment was obtained.

Corrective actions included amending the protocol and counseling the PI regarding oversight of animal research conducted by all lab members. It was noted that this animal activity was PHS-funded.

OLAW believes that the measures put in place by the Cleveland Clinic in response to the incident are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

A3047-2N

Cleveland Clinic Lerner Research Institute

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

June 1, 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 euthanized a mouse. This mouse was assigned to a protocol on which the individual was not approved to work. An amendment to add this individual to the protocol was submitted, and was approved the following day. The individual involved had been advised by the PI that animal procedures could not be conducted until the approval was obtained. Since this incident, the individual involved has relocated to a new laboratory.

The IACUC reviewed this incident at the May 15, 2018 meeting and determined that this was reportable research non-compliance. At that meeting the IACUC also requested that the Chair and Compliance Specialist meet with the PI in a face-to-face meeting. On May 24, the PI met with the IACUC Chair and the IACUC Compliance Specialist to discuss this incident and the responsibility of the PI in ensuring that the procedures that govern animal research are followed by all lab members.

The Animal Welfare Assurance number for Cleveland Clinic PHS-funded grants is A3047-01. This study is funded by NIH grant R00CA172292.

Sincerely,

(b) (6)

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

SCE/ag

The Cleveland Clinic Foundation

9500 Euclid Avenue / NB21 Cleveland, Ohio 44195 Tel 216-444-5849 Fax 216-444-3279 erzurus@ccf.org http://www.lerner.ccf.org

Wolff, Axel (NIH/OD) [E]

From: Sent: –	OLAW Division of Compliance Oversight (NIH/OD) Friday, June 01, 2018 7:21 AM
To: Cc: Subject:	OLAW Division of Compliance Oversight (NIH/OD) RE: Cleveland Clinic Noncompliance Report - 6/1/2018

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

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

From:(b) (6) @ccf.org]Sent: Friday, June 01, 2018 7:15 AMTo: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>Cc: 'accredit@AAALAC.org' <accredit@AAALAC.org>;Subject: Cleveland Clinic Noncompliance Report - 6/1/2018

Dear Dr. Morse:

Attached please find a noncompliance report from the Subcommittee for Non-compliance of the Cleveland Clinic IACUC, dated June 1, 2018.

Please acknowledge receipt.

Thank you, (b) (6)

Cleveland Clinic

(b) (6)

Please consider the environment before printing this e-mail

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