



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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  
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October 29, 2018

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

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 several instances 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 test compound was administered to mice without prior IACUC approval and a total of nineteen extremely soiled and overcrowded mouse cages on several protocols, including one expired protocol, were identified inside drawers or covered with cloth or paper at an unauthorized satellite location. Immediately upon discovery, the cages were relocated and the animals transferred to clean cages at appropriate densities. Two separate noncompliance incidents were previously identified in the same laboratory and based on the series of identified violations, the IACUC subsequently voted to suspend the four applicable animal protocols which were funded by NCI grants 5R01CA138688-09, 1R01CA229080-01A1, 5R01CA177810-04, 5R01CA187415-04 and 1R01CA219556-01A1.

The corrective actions consisted of the following:

- 1) Mandating the hire of an experienced laboratory manager for the oversight of animal activities performed by the laboratory.
- 2) Revoking the Principal Investigator's privileges to perform animal work within the laboratory.
- 3) Barring the use of all data generated from the unapproved animal activities.
- 4) Prohibiting the use of federal funds to support the care of use of the affected animals during the noncompliance and suspension periods.
- 5) Conducting unannounced post approval audits of the laboratory.

Please be advised that the PHS funding agency must be notified directly of the protocol suspensions in accordance with the NIH Grants Policy Statement. 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 being informed of these matters and find no cause for further action by this Office.

*Page 2 – Dr. Erzurum*  
*October 29, 2018*  
*OLAW Case A2047-2Q*

Sincerely,

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

cc: IACUC Chair

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 involved several issues discovered within one of our research labs. The first issue was that mice were administered an experimental agent (dextran sodium sulfate, DSS) that was not included on the approved IACUC protocol to which they were assigned. The second issue is that 19 cages were discovered to be stored in the laboratory, although laboratory housing was not part of the approved protocol. These cages were assigned to several different protocols, one of which was expired, most were heavily soiled, several were overcrowded, and a number were placed in drawers or covered with cloth or paper barriers that precluded free air flow. Upon this discovery on October 9, 2018, members of the IACUC and the Cleveland Clinic Biological Resources Unit (BRU) moved these cages to our animal facility, and placed these mice into clean cages with appropriate cage density.

The IACUC reviewed this incident at the October 16, 2018 meeting, and determined that this was reportable research non-compliance. The IACUC noted that this laboratory had two prior incidents of noncompliance, and voted to suspend all four animal protocols that are used by this laboratory. In doing so, the IACUC defined the following required elements of a corrective action plan:

- 1 – The laboratory must hire an experienced lab manager to oversee animal research activities.
- 2 – The approval to conduct animal research activities in the laboratory will be revoked.
- 3 – The laboratory may not use data collected from the animals that received DSS or were inappropriately housed in any publication that requires that animal procedures have been approved by the IACUC.
- 4 – Cage charges related to the housing of animals involved in these noncompliant activities will not be charged to any NIH award.
- 5 – In the future, the laboratory will be subject to unannounced post-approval monitoring visits and that further deficiencies could lead again to protocol suspension.

The IACUC will review the status of this corrective action plan at the January 2019 IACUC meeting or later.

The laboratory involved is supported by the following NIH awards: 5R01CA138688-09; 1R01CA229080-01A1; 5R01CA177810-04; 5R01CA187415-04; 1R01CA219556-01A1. The Animal Welfare Assurance number for Cleveland Clinic PHS-funded grants is A3047-01.

Sincerely,

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Serpil C. Erzurum, M.D.

Alfred Lerner Memorial Chair in Innovative Biomedical Research  
Chair, Cleveland Clinic Lerner Research Institute

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