From: Ward, Joan (NIH/OD) [E]
To: eric.nestler@mssm.edu

Cc: <u>iacuc@mssm.edu</u>; (b) (6) <u>Gibbens, Robert - APHIS</u>

Subject: OLAW Case A3311-H

Date: Thursday, May 2, 2019 10:34:14 AM

Attachments: 1994 001.pdf

Dear Dr. Nestler,

Attached please find Dr. Brent Morse's final response to OLAW Case A3111-H.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards, Joan

Joan Ward
Program Specialist
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 1, 2019

Re: Animal Welfare Assurance #A3111-01 (OLAW Case H)

Eric Nestler, M.D., Ph.D.
Dean for Academic Affairs
Icahn School of Medicine at Mount Sinai
Icahn Building (b) (4)
1425 Madison Avenue
New York, NY 10029-6574

Dear Dr. Nestler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 22, 2019 letter reporting an adverse event within the animal care and use program at the Icahn School of Medicine at Mount Sinai. Your letter supplements the prompt preliminary email report to OLAW sent February 4, 2019. According to the information provided it is understood that on January 30, 2019 six guinea pigs died when a cooling compressor failed that serviced an environmental chamber housing the animals. Ambient temperature within the chamber rose to 41.7 degrees Celsius resulting in hyperthermia and the death of the animals. The PI self-reported the incident and was instructed to not use the chamber until the IACUC considered the incident and made recommendations regarding future use of the repaired chamber. The animals were assigned to a PHS-funded activity.

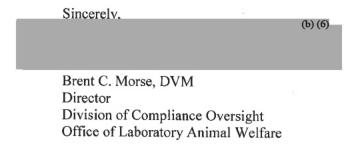
The corrective and preventive actions consisted of the following:

- The chamber must be retrofitted with a remote alarm system capable of detecting temperature changes within an appropriately restricted safety range.
- When triggered, the alarm system must have the capability to immediately send sequential alert notifications to a list of persons, including PIs and their laboratory staff, as well as supervisors of the animal facilities.
- The proper function of the alarm system must be tested before its first use, and periodically thereafter. Records of such testing must be maintained and provided in a timely fashion to Supervisors of the animal facilities.
- PIs must establish Standard Operating Procedures for training of personnel on the use of the chambers, monitoring of the animals and for responding to alarms.
- CCMS personnel will also monitor the chambers.
- The environmental chambers must to be subjected to regular preventive maintenance. Copies of the service records must be promptly provided to the CCMS Director and to Supervisors of the animal facilities.
- During semiannual inspections of the animal facilities the IACUC will conduct interviews with the chamber users and inspect all the relevant maintenance documents.

It is understood, and noteworthy, that the investigators were very cooperative with the IACUC and had preemptively started the retrofitting process for the remote alarm before being formally requested to do so by the IACUC. It is further understood that the USDA APHIS VMO has been notified of the incident.

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OLAW believes that the corrective and preventive measures put in place by the Icahn School of Medicine at Mount Sinai 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.



cc: IACUC Chair Robert Gibbens, D.V.M., USDA-APHIS-AC