



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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) 480-3387

May 12, 2020

Re: Animal Welfare Assurance
#A3596-01 (OLAW Case 3T)

Dr. Harry Orf
Senior Vice President for Research
Massachusetts General Hospital
(b) (4) 55 Fruit Street
Boston, MA 02114

Dear Dr. Orf,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 1, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Massachusetts General Hospital. According to the information provided, OLAW understands that on four occasions cages of mice were found housed outside of centralized animal facilities in non-compliance with the applicable protocol and MGH IACUC policy. In one instance animals were found dead and with no available water and other animals required euthanasia due to poor body condition. It was stated that the animal activity was not supported by the PHS, NSF or NASA.

Corrective actions included the PI and laboratory manager reviewing the IACUC Policy on Housing of Vertebrate Animals Outside of CCM Centralized Facilities, and the protocol humane endpoints, and laboratory expectations with the laboratory staff. Staff were instructed not to leave animals in the lab for more than 12 hours and signage of such instructions have been placed in the lab. The lab manager will document daily checks of the lab and report to the IACUC.

OLAW believes that the corrective measures put in place by the Massachusetts General Hospital are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals regarding the philosophy of institutional self-assessment, self-reporting and self-regulation. We do advise, due to the repeat nature of the incidents, the negative animal welfare effects and the loss of animal life, that the IACUC consider unannounced visits to the lab to verify the effectiveness of the corrective measures. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S
Date: 2020.05.12 11:31:52 -04'00'

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

cc: IACUC contact



MASSACHUSETTS
GENERAL HOSPITAL
RESEARCH INSTITUTE



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Harry W. Orf, PhD
Senior Vice President for Research
Massachusetts General Hospital
Principal Associate in Genetics
Harvard Medical School

May 1, 2020

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Room 3615, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: Serious noncompliance with PHS Policy
Institution: The Massachusetts General Hospital
Animal Welfare Assurance #: D16-00361 (A3596-01)

Dear Dr. Morse:

This letter is to provide you with a full explanation of the circumstances and actions taken by the Massachusetts General Hospital (MGH) Institutional Animal Care and Use Committee (IACUC) as required by Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) Section IV.F.3 following an incident that occurred. The incident was determined by the IACUC to constitute serious noncompliance with PHS Policy and is therefore reportable.

The incident involved mice that were on a protocol investigating tumor growth and metastasis. The mice had been injected with tumor cells on October 24, with tumor growth measured by IVIS imaging weekly. On two occasions (12/9/2019 to 12/13/2019 and 12/30/2019 to 1/5/2020), cages of mice were housed outside of centralized animal facilities, in non-compliance with the protocol and MGH IACUC policy. On the second occasion, animal care staff found 3 cages with empty water bottles. 4 mice died and 4 mice required euthanasia due to poor body condition. The remaining mice were treated and recovered.

A compliance subcommittee of the IACUC reviewed the event on February 6 and the convened IACUC reviewed the event at its monthly meeting on February 19. The PI took full responsibility for the incident and worked with the IACUC compliance officer to develop a corrective action plan to prevent a recurrence of this event.

The IACUC approved the following corrective actions:

- The PI and laboratory manager have reviewed the IACUC Policy on Housing of Vertebrate Animals Outside of CCM Centralized Facilities, and protocol's approved humane endpoints, and laboratory expectations with all laboratory staff. Staff members were instructed not to leave animals in the laboratory for more than 12 hours.

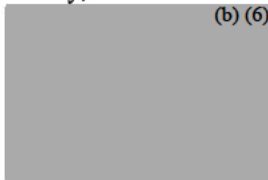
- The laboratory manager has posted signage in the imaging laboratory indicating that animals are not to be kept in the room for more than 12 hours and is documenting daily checks of the room for compliance. For 3 months, the laboratory manager will send copies of the completed room check log to the IACUC Compliance Lead
- The PI will oversee appropriate supervision of laboratory members

No PHS/NSF/NASA funds were implicated in this matter.

The Massachusetts General Hospital is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me at your convenience.

Sincerely,

(b) (6)



Harry W. Orf, PhD
Senior Vice President for Research
Institutional Official
The Massachusetts General Hospital

cc: W. Zapol MD, Chair, Institutional Animal Care and Use Committee
cc: A. Clancy PhD, Director, Animal Welfare Assurance
cc: D. Jarrell DVM, Attending Veterinarian and Director, Center for Comparative Medicine

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 4, 2020 7:39 AM
To: Clancy, Anne
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

Thank you. We will respond soon.
Axel Wolff

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Friday, May 1, 2020 2:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Orf, Harry W., Ph.D. <HORF@mgh.harvard.edu>; Jarrell, Donna M. <DJARRELL@mgh.harvard.edu>
Subject: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

Dear Dr. Morse,
Please find attached a report submitted on behalf of Dr. Harry Orf, Senior Vice President for Research and Institutional Official, The Massachusetts General Hospital, in accordance with PHS Policy IV.F.3.

Please let me know if you have any questions or require additional information.

Kind regards,
Anne Clancy

Anne Clancy, PhD | Director, Animal Welfare Assurance
Phone: (b) (6)
Fax: (b) (6)
aclancy1@mgh.harvard.edu

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