



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) 480-3387

May 12, 2020

Re: Animal Welfare Assurance
#A3596-01 (OLAW Case 3W]

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 8, 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 November 15, 2019 two rabbits underwent a minor survival surgical procedure the day after their arrival at the animal housing facility. MGH policy requires a three-day acclimation period. There was no apparent significant impact to the animals. It was stated that the animal activity was not supported by PHS/NSF or NASA funds.

Corrective actions included The PI reviewing the IACUC Policy on Quarantine and Acclimation with the lab manager and they will ensure that all members of the research team adhere to the policy.

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. 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 11:33:39 -04'00'

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

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC



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 8, 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 research study involves the use of a novel intravascular fluorescence catheter to study high-risk atheromatous plaque biology in vivo. The incident occurred on November 15 and involved 2 rabbits that underwent a minor survival surgical procedure the day after their arrival in the animal housing facility. MGH policy requires a 3-day acclimation period. Immediate actions included alerting the research team to the error. A review of the medical record did not identify any significant impact on the animals.

The incident was reported to the IACUC on November 18. The Director, Animal Welfare Assurance and the Attending Veterinarian reported the incident to the USDA VMO on November 22. A compliance subcommittee of the IACUC reviewed the event on March 5 after the medical record review was complete and the convened IACUC reviewed the event at its monthly meeting on March 18. 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 action:

- The PI has reviewed the IACUC Policy on Quarantine and Acclimation with the laboratory manager and they will ensure that all members of the research team adhere to the policy

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

Brent Morse, DVM Ltr.
May 8, 2020

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 11, 2020 11:00 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 for this report, Dr. Clancy. We will respond soon.
Axel Wolff

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Friday, May 8, 2020 2:20 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

For 24/7 assistance with critical research matters, call 617-726-HOW2 (4692)

Have an idea or a suggestion on how we can improve? Please submit a suggestion to Isuggest !
Isuggest

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