



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

February 19, 2020

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

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 letter dated January 30, 2020, concerning a report of an incident of noncompliance with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals within the animal care and use program at Massachusetts General Hospital. According to the information provided, OLAW understand that on October 1, 2019, three mice did not receive postoperative analgesics as described in the animal study protocol (ASP). The mice were also under another of the PI's protocol. This work was not PHS funded.

Corrective and preventive actions included reviewing and amending the ASP, reviewing rodent records and other CCM cards, and enhanced oversight of the next three procedures.

Massachusetts General Hospital's prompt reporting of this incident was consistent with the philosophy of self-regulation. Similarly, the timely actions taken to respond to the issue were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Catharine E. Pritchard, PhD  
Animal Welfare Policy Scientist  
Division of Policy and Education  
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3596-30



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

January 30, 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 occurred on October 1 and involved 3 mice that were on a protocol investigating vascular injury models. The animals underwent a carotid ligation surgery. Analgesics were administered immediately after the procedure, but a second dose was not administered the following morning, as required by the treatment plan in the protocol. The facility veterinarian noted the animals appeared to be experiencing pain and directed the fellow to immediately administer the analgesics and reported the event to the IACUC. The PI and the research team met with the IACUC compliance officer and the facility veterinarian on November 14 to review the incident. At that time, it also became apparent that the procedure performed was approved on another of the PI's protocols, and not on the protocol these animals were under due to an oversight by the fellow. A compliance subcommittee of the IACUC reviewed the event on December 5 and the convened IACUC reviewed the event at its monthly meeting on December 18. No more surgeries were conducted while the incident was under investigation.

The IACUC approved the following corrective actions:

- Amending the protocol to add the carotid ligation model.
- Reviewing each protocol with laboratory personnel to ensure that they understand what is approved on each protocol.
- Consulting with the facility veterinarian to review analgesia plan.
- Reviewing the use of rodent record cards and other CCM cards with all members of the research team. The rodent record card is used as a tool to ensure, and document, compliance with the treatment and monitoring plan of the approved protocol.
- For the next three (3) procedures on the protocol, the laboratory will provide documentation to the IACUC compliance officer, for her review, to demonstrate compliance with the approved IACUC protocol for adherence to the procedure as well as to post procedure monitoring and care.

No PHS/NSF 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

## **Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, January 31, 2020 1:18 PM  
**To:** Clancy, Anne; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Orf, Harry W., Ph.D.; Jarrell, Donna M.  
**Subject:** RE: Report of Serious Noncompliance with PHS Policy\_Massachusetts General Hospital\_AWA # D16-00361 (A3596-01)

Thank you for this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Clancy, Anne [mailto:ACLANCY1@mgh.harvard.edu]  
**Sent:** Thursday, January 30, 2020 1:30 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)  
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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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