



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

November 9, 2020

Re: Animal Welfare Assurance
#A3596-01 (OLAW Case 4D]

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 October 8, 2020 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Massachusetts General Hospital. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that 28 mice had tail snips performed for genotyping without anesthesia. Anesthesia was required for the animals based on their age (they were over 21 days old). The mice were not part of a PHS-funded study.

Corrective actions consisted of retraining the laboratory members involved and having them meet with the veterinarian and IACUC compliance lead. The veterinarian and compliance lead worked with the laboratory to standardize mouse genotyping procedures, ensure that institutional policy requirements are met, and implemented the use of institutional standard procedure forms. The Principal Investigator, on the recommendation of the veterinarian, switched to genotyping by ear punch, invested in equipment needed to make this change, and submitted the necessary amendments to the animal activities.

OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. The application of careful oversight and PHS Policy standards to non-PHS funded activities is in keeping with the philosophy of self-regulation. We commend your institution for continuing to evaluate and improve your compliance program. Please contact our office if the corrective actions are not carried out as described. We appreciate having been informed of this matter and at this time find no cause for further action by this Office.

Sincerely,

Nicolette A.
Petervary -S

Digitally signed by Nicolette A.
Petervary -S
Date: 2020.11.09 08:32:41 -05'00'

Nicolette Petervary, VMD, DACAW
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC Contact



55 Fruit Street, Bul240E
Boston, MA 02114
Phone: 617-724-9079
Fax: 617-724-3307
Email: horf@mg.harvard.edu

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

October 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 incident involved a protocol studying novel Alzheimer's disease candidate genes in mouse models for the disease. The incident occurred on July 29 and involved 28 mice that had tail snip biopsies performed. At the time of the biopsy, the animals were older than 21 days of age. MGH requires anesthesia and analgesia for these older animals, which had not been used.

The Principal Co-Investigator (Co-I) and the technician who performed the procedure met with the IACUC compliance lead and the facility veterinarian on August 3 to review the incident. A compliance subcommittee of the IACUC reviewed the incident on August 6 and the convened IACUC reviewed the event at its monthly meeting on August 19. During the meeting it was noted that the laboratory has multiple IACUC protocols with different approved methods for genotyping described in the various protocols. It was agreed the laboratory should standardize methodologies across protocols, considering the age at which mice may need to be genotyped and the corresponding institutional requirements that apply.

The IACUC approved the following corrective actions:

- The laboratory's IACUC protocols were amended to include institutional standard procedure forms for tail snipping and ear punching; the laboratory decided to transition to ear punch at the recommendation of the facility veterinarian and invested in recommended equipment for that procedure;
- The research technician for the lab received training from the animal program training manager on these techniques.

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October 8, 2020
Brent Morse, DVM Ltr.

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)

A large rectangular area of the document is redacted with a solid grey box, covering the signature and any handwritten notes.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 14, 2020 8:14 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 send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Tuesday, October 13, 2020 4:43 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](#) !
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