



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 21, 2020

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

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 January 14, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Massachusetts General Hospital. According to the information provided, OLAW understands that nine mice had microelectrodes implanted and were maintained for several months but were not adequately monitored which led to the formation of granulation tissue around the implant. The person responsible for monitoring had left the laboratory and the responsibility had not been transferred to another laboratory member.

The corrective actions consisted of euthanizing the mice, having the Principal Investigator (PI) enforce the laboratory's transition plan for staff turnover, having the PI institute a weekly animal census, having laboratory staff check implanted animals weekly and clean implants as needed, and providing copies of the census checks to the Institutional Animal Care and Use Committee.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



MASSACHUSETTS
GENERAL HOSPITAL

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January 14, 2020



HARVARD
MEDICAL SCHOOL

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

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)
NIH/NSF Grant(s): 5R01NS091390-05

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 9 mice that had undergone microelectrode implant surgery between 5/19/2019 and 6/6/2019. Mice are kept for up to three months after surgery for testing purposes. On 8/23/2019, the mice were found with tissue granulation around the implants requiring euthanasia. The Principal Investigator (PI) met with the IACUC compliance officer and the facility veterinarian on November 12 to review the event, when the PI was first available. A review of study documentation confirmed that all animals had received appropriate post-operative pain management per the approved protocol. However, the PI noted that the longer-term oversight of the animals was not transitioned to another member of the research team when the fellow responsible for the animals left the laboratory abruptly. 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. The investigator provided additional information that was reviewed by the IACUC at its convened meeting on January 15. The committee determined there was impact on animals and therefore the event was reportable.

The IACUC approved the following corrective actions that were put in place with the PI:

- The PI reinforced that laboratory's transition plan for when a member of the laboratory leaves;

- The PI instituted a weekly census of all animals. The laboratory staff examines the status of all implanted animals at least weekly (and clean implants as needed) to ensure animal welfare. Immediately following the incident, at the direction of the IACUC, copies of the census checks were provided to IACUC compliance officer for review. The laboratory will continue to document census of the animals which are available for review by the IACUC.

The institution will ensure that applicable costs paid from the NIH grant will be removed, and the relevant agencies will be notified, as appropriate.

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
cc: (b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 21, 2020 7:00 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 send a response soon.

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

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Thursday, February 20, 2020 4:33 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)

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