



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

January 17, 2020

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

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

Dear Dr. Orf,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2019 letter describing a noncompliance at your institution with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This letter had not been preceded by a preliminary report to OLAW. According to the information provided, our office understands that on September 6, 2019 a member of the Institutional Animal Care and Use Committee (IACUC) observed a research fellow failing to employ aseptic technique while performing survival surgery in a mouse. This deviated from the approved protocol and from IACUC policy. The mouse was part of a PHS activity.

Corrective measures consisted of immediately euthanizing the mouse. In addition, the Principal Investigator (PI) met with the IACUC compliance officer and the institution's veterinarian to discuss the issue. The PI reviewed aseptic technique with the research team and stated he will continue to emphasize strict adherence. The institution's veterinarian also provided hands on training to the research team. An IACUC subcommittee subsequently met to review the corrective measures. In addition to the measures outlined above, the IACUC subcommittee required additional CITI training on aseptic technique, supervision of new laboratory members by experienced staff, and better sanitation of the surgical space, which will be evaluated by a compliance officer prior to the next surgery. The IACUC will also perform unannounced visits over the next six months to ensure appropriate cleanliness of the surgical space and adherence to aseptic technique.

OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and at this time find no cause for further action by this office.

Sincerely,

(b) (6)

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

CC: IACUC Contact



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HARVARD
MEDICAL SCHOOL

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

December 13, 2019

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): 5R21NS101311-02

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 research fellow who was observed by an IACUC officer performing survival surgery on a single mouse without using aseptic precautions, which was in non-compliance with the approved protocol and IACUC policy. The animal was euthanized immediately.

The incident occurred on September 6. The Principal Investigator (PI) met with the IACUC compliance officer and the facility veterinarian on September 30 to review the event. At that meeting the PI noted that this was the first time the fellow did not use aseptic precautions as required and that the requirements for rodent survival surgery had been reviewed with the research team. The PI also stated he will continue to emphasize strict adherence to aseptic technique with the group. The facility veterinarian provided hands-on aseptic surgery training to the research team on October 29.

A compliance subcommittee of the IACUC reviewed the event on November 7 and the convened IACUC reviewed the event at its monthly meeting on November 20.

In addition to the actions taken by the PI, the IACUC approved additional corrective actions:

- All protocol study staff were required to retake the CITI Aseptic Surgery course
- The PI or an experienced laboratory member was required to supervise new personnel as they learn and practice the approved surgical procedures
- There was concern expressed about the general cleanliness of the laboratory research space. The PI was required to ensure that the laboratory surgical space be kept at the appropriate level of cleanliness, as described in the Rodent Survival Surgery Checklist and the inspection checklist, both of which were provided to the PI. The IACUC compliance officer will review the space prior to the next surgery.
- The IACUC will conduct unannounced checks of the space over the next 6 months to ensure the laboratory is maintained appropriately and aseptic precautions are in use. The laboratory may lose the privilege to conduct rodent surgeries in the laboratory space if concerns persist.

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: Wednesday, December 18, 2019 6:51 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 Dr. Clancy. We will respond soon.
Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Tuesday, December 17, 2019 4:24 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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