



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 8, 2020

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

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 31, 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 October 15, 2019 it was found that five mice had been improperly euthanized using CO₂. A research staff member left the building during the procedure and a building staff member found the animals and completed the euthanasia. It was stated that the animal activity was not supported by PHS or NSF funds.

Corrective actions included The PI counseling the research group regarding proper euthanasia technique and responsibilities and focused on the correct procedures at the next laboratory meeting.

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: 2020.05.08 09:26:52 -04'00'

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

cc: IACUC contact



MASSACHUSETTS
GENERAL HOSPITAL

RESEARCH INSTITUTE

55 Fruit Street, Bul 240E
Boston, MA 02114-2696
Tel: 617-724-9079
Fax: 617-724-3377
E-mail: horf@mgm.harvard.edu



HARVARD
MEDICAL SCHOOL

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

January 31, 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 14 and involved the euthanasia of 5 mice that was not conducted in accordance with institutional policy. The animals were euthanized by carbon dioxide overdose. The responsible scientist exposed the mice to the gas and then left the facility. IACUC policy requires that animals not be left unattended during euthanasia and death must be confirmed. A facility staff member found the mice and completed the euthanasia procedure. Because there were no identifiers on the cage an investigation was initiated to identify the responsible party. The PI and the lab's research assistant met with the IACUC compliance officer and the facility veterinarian on November 26 to review the incident. 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 PI retrained the research staff on the IACUC Policy on Euthanasia and counseled the group on appropriate procedure and responsibility when performing euthanasia. The PI communicated to the team by email immediately after the event and focused on correct procedure at the next laboratory meeting on December 5. The IACUC approved this corrective action.

No PHS/NSF funds were implicated in this matter.

Page 2
January 31, 2020
Brent Morse, DVM ltr.

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: Friday, May 1, 2020 7:37 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)

Hi Ms. Clancy,

I looked in the archives and could not find this case, so I appreciate you sending it to us. We'll handle this like a new submission and send a reply soon.

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

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Thursday, April 30, 2020 10:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

Dear OLAW-

I am working on MGH IACUC compliance matters and went through my files. I do not have a record of receiving a response from OLAW for the attached report, submitted Jan 31, 2020. Internally at MGH we labeled this report 2020-03. I would like to confirm the status of this report with OLAW. I apologize in advance if I missed a communication.

Thank you-
Anne

Anne Clancy, PhD | Director | Office of Animal Welfare Assurance
Massachusetts General Hospital Research Institute
(b) (4) | 149 13th Street | Charlestown, MA 02129
(b) (6) desk) | (b) (6) (cell)
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!](#)

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Friday, January 31, 2020 1:57 PM
To: 'olawdco@mail.nih.gov' <olawdco@mail.nih.gov>
Cc: Orf, Harry W., Ph.D. <HORF@mgh.harvard.edu>; Jarrell, Donna M. <DJARRELL@mgh.harvard.edu>
Subject: RE: 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

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Partners Compliance HelpLine at <http://www.partners.org/complianceline> . If the e-mail was sent to you in error but does not contain patient information, please contact the sender and properly dispose of the e-mail.

Wolff, Axel (NIH/OD) [E]

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Friday, May 1, 2020 9:23 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

Dr. Wolff-sounds good, thank you.

Best to OLAW – we appreciate your support of assured institutions during this time.

Regards-
Anne

Anne Clancy, PhD | Director | Office of Animal Welfare Assurance
Massachusetts General Hospital Research Institute
(b) (4) | 149 13th Street | Charlestown, MA 02129
(b) (6) (desk) | (b) (6) (cell)
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!](#)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, May 1, 2020 7:37 AM
To: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

External Email - Use Caution

Hi Ms. Clancy,

I looked in the archives and could not find this case, so I appreciate you sending it to us. We'll handle this like a new submission and send a reply soon.

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

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Thursday, April 30, 2020 10:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Report of Serious Noncompliance with PHS Policy_Massachusetts General Hospital_AWA # D16-00361 (A3596-01)

Dear OLAW-

I am working on MGH IACUC compliance matters and went through my files. I do not have a record of receiving a response from OLAW for the attached report, submitted Jan 31, 2020. Internally at MGH we labeled this report 2020-03. I would like to confirm the status of this report with OLAW. I apologize in advance if I missed a communication.

Thank you-
Anne

Anne Clancy, PhD | Director | Office of Animal Welfare Assurance
Massachusetts General Hospital Research Institute
(b) (4) | 149 13th Street | Charlestown, MA 02129
(b) (6) (desk) | (b) (6) (cell)
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!](#)

From: Clancy, Anne <ACLANCY1@mgh.harvard.edu>
Sent: Friday, January 31, 2020 1:57 PM
To: 'olawdco@mail.nih.gov' <olawdco@mail.nih.gov>
Cc: Orf, Harry W., Ph.D. <HORF@mgh.harvard.edu>; Jarrell, Donna M. <DJARRELL@mgh.harvard.edu>
Subject: RE: 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!](#)

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Partners Compliance HelpLine at <http://www.partners.org/complianceline>. If the e-mail was sent to you in error but does not contain patient information, please contact the sender and properly dispose of the e-mail.