



## USDA-APHIS-Animal Care



| ANIMAL WELFARE COMPLAINT  |   |   |                           |
|---|---|---|---------------------------|
| Complaint No.<br>AC19-345   | Date Entered:<br>4-Jun-19   | Processed By:<br>ERF                              |                           |
| Referred To:<br>Karr / Hadjis   |   | Reply Due:<br>6-Jul-19                            |                           |
| Facility or Person Complaint Filed Against  |   |   |                           |
| Name:<br>Massachusetts Eye And Ear Infirmary  |   | Customer No.:<br>119                              | License No.:<br>14-R-0022 |
| Address:<br>243 CHARLES STREET  |   | Email Address:                                    |                           |
| City:<br>Boston   | State:<br>MA  | Phone No.:<br>(617) 799-2659                      |                           |
| Complainant Information   |   |   |                           |
| Name:<br>(b) (6), (b) (7)(C), (b) (7)(D)  |   | Organization:<br>(b) (6), (b) (7)(C), (b) (7)(D)  |                           |
| Address:<br>(b) (6), (b) (7)(C), (b) (7)(D)   |   | Email Address:<br>(b) (6), (b) (7)(C), (b) (7)(D) |                           |
| City:<br>(b) (6), (b) (7)(C), (b) (7)(D)  | State:<br>(b) (6), (b) (7)(C), (b) (7)(D)                                     | Phone No.:<br>(b) (6), (b) (7)(C), (b) (7)(D)     |                           |
| How was the Complaint received?<br>Email  |   |   |                           |
| Details of Complaint:<br><b>SEE ATTACHED</b>  |   |   |                           |
| <b>Results:</b><br>This incident was self-reported to USDA / APHIS / Animal Care by the facility within five days. The facility investigated the incident, and has taken corrective actions to prevent a recurrence. This incident was reviewed by Animal Care inspectors on inspection of the facility, report dated October 17, 2018. No NCIs were cited based on the Tech Note for "Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance."<br><br>We will continue to inspect this facility to ensure AWA-regulated animals are protected to the fullest extent of Federal law. |   |   |                           |
| Application Kit Provided:<br>Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>  |   |   |                           |
| Inspector:<br><b>EILIS KARR</b>   | Digitally signed by EILIS KARR<br>Date: 2019.07.08 15:08:00 -04'00'           |   | Date:                     |
| Reviewed By:<br><b>Tonya Hadjis, DVM</b>  | Digitally signed by Tonya Hadjis,<br>DVM<br>Date: 2019.07.09 09:50:10 -04'00' |   | Date:                     |



Animal and Plant  
Health Inspection  
Service

June 4, 2019

Animal Care  
4700 River Road  
Riverdale, MD 20737

(b) (6), (b) (7)(C), (b) (7)(D)

Dear Complainant,

Thank you for your correspondence dated 8-Feb-19. We are reviewing your concerns and assigned tracking number AC19-345. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publically available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: <https://efoia-pal.usda.gov/App/Home.aspx>
2. Fax: 301-734-5941
3. US Mail:  
USDA- APHIS- FOIA  
4700 River Road, Unit 50  
Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102.**

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Betty Goldentyer  
Associate Deputy Administrator  
Animal Care

**Fausch, Emily R - APHIS**

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**From:** Goldentyer, Betty J - APHIS  
**Sent:** Friday, February 8, 2019 1:28 PM  
**To:** ACEAST  
**Cc:** Whisenton, Katie M  
**Subject:** FW: Official Complaint -- Massachusetts Eye and Ear Infirmary

**From:** (b) (6), (b) (7)(C), (b) (7)(D)  
**Sent:** Friday, February 8, 2019 12:45 PM  
**To:** Goldentyer, Betty J - APHIS <Betty.J.Goldentyer@aphis.usda.gov>  
**Cc:** ACE <ACE@aphis.usda.gov>  
**Subject:** Official Complaint -- Massachusetts Eye and Ear Infirmary

(b) (6), (b) (7)(C), (b) (7)(D)

Dr. Elizabeth Goldentyer  
USDA/APHIS/AC  
920 Main Campus Drive, Suite 2000  
Raleigh, NC 27606

2/8/19

Dr. Goldentyer,

I am writing to you today to file an Official Complaint against Harvard University's Massachusetts Eye and Ear Infirmary (14-R-0022 ) for serious violations of the Animal Welfare Act. This complaint is based on communications between the Harvard University department of Otology and Laryngology (relevant to the Massachusetts Eye and Ear Infirmary) and the Office of Laboratory Animal Welfare. A 8/7/18 letter states:

***"On June 20, 2018 a quorum of the Mass Eye and Ear Institutional Animal Care and Use Committee (IACUC) found, by a unanimous vote that a laboratory conducted a reportable violation of our Institute's PHS Assurance . . . The committee voted unanimously that a PI committed the following violation:***

***Upon review of the disposition records for gerbils, the Attending Veterinarian noted that there were 7 unexpected deaths (prior to the experimental endpoint) that resulted from a terminal apical surgical approach for accessing the cochlear. After further discussions with the laboratory personnel, it was noted that the description of the surgical approach in the protocol was not clear. It was determined that the personnel performing the procedure needed a better understanding of the procedure and also needed further hands-on training for the specific technique."***

It is very clear, from the language used in the report, that this incident is a violation of PHS policy on animal care, which for a regulated species like gerbils, is equivalent to the Animal Welfare Act. And so, since this is a



regulated species under the Animal Welfare Act, since the PHS policy was violated, the Animal Welfare Act must also have been violated.

The seriousness of this violation is further underlined by the fact that the IACUC also saw fit to refund grant money (over \$2000) back to the National Institutes of Health. This step is only taken relevant to the most serious violations.

Therefore, based on the text of the letter, it is clear that the staff was not qualified to perform this procedure because ***"It was determined that the personnel performing the procedure needed a better understanding of the procedure and also needed further hands-on training for the specific technique."***

Therefore, this is a clear failure to comply with Sec. 2.32 Personnel Qualifications, because animals died due to the inability of Harvard Medical School/Massachusetts Eye & Ear Infirmary Staff to perform this surgical procedure correctly.

The fact that these animals died during a medical procedure also demonstrates a violation of Sec. 2.38 Miscellaneous (f)(1) Animal Handling because Harvard Medical School/Massachusetts Eye & Ear Infirmary staff clearly "failed to handle gerbils in a manner that did not cause trauma or physical harm to the animals."

It is also clear, due to the text which states: " . . . ***it was noted that the description of the surgical approach in the protocol was not clear.***"

It is very obvious that the Institutional Animal Care and Use Committee did not adequately review this protocol as is required in Sec. 2.31 Institutional Animal Care and Use Committee (IACUC). (d) IACUC review of activities involving animals.

Major violations of the Animal Welfare Act are considered to be very serious in nature, especially when the violations cause distress/injury/death to animals. I must insist that you take the most severe action allowable under the Animal Welfare Act and begin the process of launching a thorough investigation, and at the conclusion of the investigation, issue the maximum allowable fine of \$10,000 per infraction/per animal against Harvard Medical School's Massachusetts Eye & Ear Infirmary. I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

Attachments: Multiple NIH Reports

(b) (6), (b) (7)(C), (b) (7)(D)



**Massachusetts  
Eye and Ear**

August 7, 2018

Brent Morse, D.V.M., DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
Bethesda, MD 20892-7982

Dear Dr. Morse,

On June 20, 2018 a quorum of the Mass Eye and Ear Institutional Animal Care and Use Committee (IACUC) found, by a unanimous vote, that a laboratory conducted a reportable violation of our Institute's PHS Assurance #D16-00215.

The committee voted unanimously that a PI committed the following violation:

Upon review of the disposition records for gerbils, the Attending Veterinarian noted that there were 7 unexpected deaths (prior to the experimental endpoint) that resulted from a terminal apical surgical approach for accessing the cochlear. After further discussions with the laboratory personnel it was noted that the description of the surgical approach in the protocol was not clear. It was determined that the personnel performing the procedure needed a better understanding of the procedure and also needed further hands-on training for the specific technique.

This is an NIDCD-funded protocol (grant number: 2R01DC007910)

The Committee reviewed the issue of non-compliance at a convened meeting and noted that the following actions would be taken before any more animals can be purchased and any new surgical procedures can be performed:

- An amendment that further describes and clarifies the surgical procedures performed for accessing the cochlea needs to be submitted and approved by the IACUC.
- Training for all lab personnel that will perform this surgical procedure has to be scheduled with an experienced animal user named by the Committee, who has agreed to train the staff in performing the apical exposure of the cochlea. Members of the Animal Care Facility Veterinary Staff must be present for these training sessions.
- Once the trainer and the Animal Care Facility Veterinary Staff have observed and documented that lab members have been adequately trained on the procedure, the lab will need to notify the Animal Care Facility Veterinary Staff in advance of performing any future terminal surgeries. Animal Care Facility Veterinary Staff will discontinue their monitoring activities after at least three successful outcomes for this procedure.



Harvard Medical School Affiliates

If you have any further comments or questions, please contact me at  
(b) (6), (b) (7)(C) email harvard.edu or by phone at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

cc:

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)





HARVARD MEDICAL SCHOOL  
DEPARTMENT OF OTOTOLOGY AND LARYNGOLOGY

MASSACHUSETTS EYE AND EAR INFIRMARY

Eaton-Peabody Laboratory  
243 Charles Street, Boston MA 02114-3096



September 24, 2018

Eric Nunn  
Grant Management Specialist  
NIH - NIDCD  
NSC BG RM 8324 6001 EXECUTIVE BLVD ROCKVILLE MD 20852

RE: Notification of IACUC Protocol Noncompliance / 2R01DC007910-10 (b) (6), (b) (7)(C) Measuring  
and Modeling the Cochlear Motions that Drive the Inner and Outer Hair Cells and Produce Otoacoustic  
Emissions

Dear Mr. Nunn:

Please be advised that on August 8, 2018 the NIH Office of Laboratory Animal Welfare (OLAW) was  
notified by Massachusetts Eye & Ear Infirmary (MEEI) of an incident of noncompliance related to activities  
performed under the NIH-NIDCD funded grant 2R01DC007910-10.

In accordance with the Public Health Service (PHS) Guidance on Confirming Appropriate Charges during  
the period of Noncompliance for Activities Involving Animals, the purpose of this letter is to inform you of  
the financial adjustments that have been made to remove any unallowable charges from the grant, per the  
above PHS Guidance. Charges related to the conduct of activities involving animals during the period of  
noncompliance have been removed from the above referenced grant as follows:

Animal Purchases (Female Mongolian Gerbils) = \$1,215.81

Animal Housing Facility Fee for the Months March - July) = \$832.38

Attached please find our correspondence with OLAW on this matter. MEEI remains committed to  
performing all animal related research in full compliance with applicable regulations. Let us know if you  
have any questions or need additional information.

Sincerely,



Signature of Dr. David P. Orr  
Dr. David P. Orr, M.D., M.Sc.  
Director, Eaton-Peabody Laboratory  
243 Charles Street, Boston, MA 02114  
Phone: 617-624-5000

(b) (6), (b) (7)(C)

243 Charles Street,  
Eaton Peabody Laboratory  
Boston MA, 02114



