



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive – MSC 7982  
Bethesda, Maryland 20892-7982  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

June 7, 2017

Re: Animal Welfare Assurance  
A3551-01 [OLAW Case X]

Mr. Michael F. Malone  
Vice Chancellor for Research and Engagement  
University of Massachusetts-Amherst  
Whitmore Administration Building  
181 Presidents Drive  
Amherst, MA 01003-9313

Dear Dr. Malone,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 31, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Massachusetts - Amherst. Your letter supplements the initial phone call report on May 15, 2017. According to the information provided, OLAW understands that in April 2017, the IACUC became aware that post-operative analgesia (buprenorphine) had not been administered to several hundred mice as required by the protocol. It is understood that the activity was funded by the PHS.

The corrective actions consisted of notifying the PI of the requirement to adhere to the protocol and of how to obtain the approved analgesic agent. Information on alternative analgesic agents was provided to the PI and the PI was notified that a change in analgesics would require a protocol amendment. The IACUC will place more emphasis on the review of surgical records and the Compliance Specialist will monitor the surgical records on this project on a monthly basis for six months. The funding component has been notified of the issue.

OLAW believes that the corrective measures put in place by the University of Massachusetts – Amherst are appropriate for this incident. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

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

cc: IACUC Contact



**University of Massachusetts  
Amherst**

IACUC office  
Mass Venture Center, Room 217  
100 Venture Way  
Hadley, MA 01035

Office of the Vice Chancellor for Research  
& Engagement

voice: 413.545.0668  
fax: 413.577.1728

May 31, 2017

Dr. Brent Morse, D.V.M.  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Re: PHS Assurance # D16-00337

Dear Dr. Morse,

In compliance with PHS policy, I am writing to provide you with this **Final Report** regarding the matter of non-compliance first reported to you by **secondary Individual** Research Compliance Specialist, on May 15, 2017. The report pertained to research funded by NIH award # 5 R00CA163671 and covered by IACUC approved protocol # 2014-0032.

A subcommittee of The University of Massachusetts Amherst's Institutional Animal Care and Use Committee (IACUC) reviewed facts around this matter. The following is a summary:

- During a semi-annual IACUC inspection, surgical records in a shared surgical area were noted as incomplete.
- While meeting with the PI and lab members to review proper completion of records, it was discovered that analgesia as described in the protocol was not being administered for surgical procedures.

**Actions taken:**

- The PI was immediately notified that he must adhere to the protocol.
- The PI was provided information on how to obtain the analgesic agent that he was currently approved to use.
- The PI was provided information on alternative analgesic agents.
- The PI was notified that if he wished to switch to an alternate analgesic agent, an amendment would be required.
- The IACUC evaluated its current monitoring program and will place more emphasis on the review of surgical records.
- For continuation of this research project, the Compliance Specialist will monitor surgical records on a monthly basis for the next 6 months.

Continued and enhanced communication with the PI will confirm that analgesia will be used and documented appropriately in all future procedures.

Should you have further questions or need additional information, please do not hesitate to contact us.

Sincerely,



Michael F. Malone  
Vice Chancellor for Research & Engagement  
Institutional Official

Cc: Jesse Mager, IACUC Chair  
Secondary Individual Asst. VC for Research & Engagement, Compliance & Support Services  
Secondary Individual Research Compliance Specialist  
Martinson Owusu, Grants Management Specialist  
Nastaran Kuhn, Program Officer

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, June 05, 2017 1:50 PM  
**To:** Secondary Individual  
**Subject:** RE: PHS Assurance # D16-00337 report #2

Thank you. We will respond soon.  
Axel Wolff

**From:** Secondary Individual [mailto:Secondary Individual@research.umass.edu]  
**Sent:** Monday, June 05, 2017 1:42 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Vice Chancellor for Research and Engagement <vcre@umass.edu>; Secondary Individual@research.umass.edu; jmager@vasci.umass.edu; Secondary Individual@research.umass.edu; Owusu, Martinson (NIH/NCI) [E] <martinson.owusu@nih.gov>; Kuhn, Nastaran (NIH/NCI) [E] <nas.kuhn@nih.gov>  
**Subject:** PHS Assurance # D16-00337 report #2

Dear Dr. Morse,

Pursuant to the preliminary phone report on May 15, 2017, please find attached a final report on use of analgesia.

Regards,

Secondary Individual  
Research Compliance Specialist  
University of Massachusetts  
Room # Mass Venture Center  
100 Venture Way  
Hadley, MA 01035  
Phone Number

A3551-X



## Initial Report of Noncompliance

By: *[Signature]*

Date: 5/15/17

Time: 4:15

Name of Person reporting

Secondary Individual

Telephone #

Phone Number

Fax #:

Email:

Name of Institution:

Assurance number:

*U Mass - Amherst*  
*A3551*

Did incident involve PHS funded activity?

*Yes*

Funding component:

Was funding component contacted (if necessary):

What happened? *Over several months Buprenorphine not given post op to ~ 300 mice.*

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

*No*

Projected plan and schedule for correction/prevention (if known):

*Counseling + modify protocol to use meloxicam.*

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_