



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

August 30, 2022

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

Dr. Michael F. Malone
Vice Chancellor for Research and Engagement
University of Massachusetts-Amherst
(b) (4) Whitmore Admin. Building
181 Presidents Drive
Amherst, MA 01003

Dear Dr. Malone,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 26, 2022 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 your prompt preliminary report on August 19, 2022. According to the information provided, OLAW understands that a surgery protocol involving rats is approved for a minimum of two doses of analgesic. Three animals only received one dose of analgesic. One surgeon did not have surgery listed in their role on the protocol. The associated activity is funded by the NIH and also by NSF awards 1835268 and 1942176.

The corrective and preventive measures included the PI being notified of the non-compliance; all surgeons and the PI will repeat the surgery training including hands on surgery training, surgery records training, online modules, and a quiz component. The PI was reminded to ensure personnel roles are accurately defined on the protocol; an amendment was submitted.

OLAW believes that the corrective and preventive 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

-S

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2022.08.30 09:43:12
-04'00'

cc: IACUC contact
NSF Animal Welfare Officer

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Tuesday, August 30, 2022 9:54 AM
To: Vice Chancellor for Research and Engagement
Cc: OLAW Division of Compliance Oversight (NIH/OD); jmager@vasci.umass.edu;
(b) (6)
Subject: OLAW Case A3551-1I
Attachments: A3551-1I.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Good morning Dr. Malone,

Attached please find Dr. Morse's response to OLAW Case A3551-1I. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

August 26, 2022

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 (A3551-01)

Dear Dr. Morse,

In accordance with PHS policy, I provide you a **Final** report of non-compliance. The initial report was sent on August 19, 2022. This pertains to research funded by NIH award 5R21MH122798-02 and NSF awards 1835268 and 1942176, covered by IACUC approved protocol #1765 at the University of Massachusetts Amherst.

The protocol involves intracranial surgeries on rats and is approved for a minimum of two doses of analgesic. Three animals only received one dose of analgesic. One surgeon did not have surgery listed in their role on the protocol.

The corrective measures and status of completion are as follows:

- PI was been notified of non-compliance on **8/16/22** by phone.
- PI was sent OLAW's guidance on reporting and confirmed receipt and understanding of information by email on **8/19/22**.
- All surgeons and PI will repeat the surgery training. There are several components to training:
 - PI and surgeons are all registered for hands on surgery training on **9/12/22** and **9/30/22**.
 - Surgery records training was completed by all surgeons on **8/23/22** and the PI is scheduled to take on **8/29/22**.
 - Online modules are in progress by all members.
- A quiz component was added to the surgery records training to ensure competency on **8/17/22**.
- PI has been reminded to ensure personnel roles are accurately defined on the protocol; an amendment was submitted on **8/18/22**.

Please contact us if there are questions. We look forward to your response.

Sincerely,

(b) (6)

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

cc:

Jesse Mager, IACUC Chair

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: Vice Chancellor for Research and Engagement <vcre@umass.edu>
Sent: Friday, August 26, 2022 1:33 PM
To: OLAW Division of Compliance Oversight (NIH/OD); McCoy, Devora (NIH/OD) [E]
Cc: Jesse Mager; (b) (6) Vice Chancellor for Research and Engagement
Subject: [EXTERNAL] PHS Assurance #D16-00337 (A3551-01)
Attachments: 2022 August UMass Final Report to OLAW.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Morse,

In accordance with PHS policy, I provide you a **Final** report of non-compliance. The initial report was sent on August 19, 2022. This pertains to research funded by NIH award 5R21MH122798-02 and NSF awards 1835268 and 1942176, covered by IACUC approved protocol #1765 at the University of Massachusetts Amherst. Please find the attached letter with more information.

Regards,
Mike

Michael F. Malone
Vice Chancellor for Research & Engagement
University of Massachusetts Amherst

(b) (6)

(b) (6)

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August 19, 2022

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 (A3551-01)

Dear Dr. Morse,

In accordance with PHS policy, I provide you a preliminary report of non-compliance. This pertains to research funded by NIH award 5R21MH122798-02 and NSF awards 1835268 and 1942176, covered by IACUC approved protocol #1765 at the University of Massachusetts Amherst.

This protocol involves intracranial surgeries on rats. The protocol is approved for a minimum of two doses of analgesic. During post approval monitoring, surgery records for three animals were found with only one dose of analgesic given. One surgeon did not have surgery listed in their role on the protocol.

The corrective measures are as follows:

- PI has been notified of non-compliance.
- PI was sent OLAWs guidance on reporting and will confirm they have reviewed it.
- All surgeons and PI will be required to repeat the surgery training.
- A quiz component has been added to the surgery records training to ensure competency.
- PI has been reminded to ensure personnel roles are accurately defined on the protocol and will review all protocols for accuracy.

I expect to send you a final report by August 26, 2022. Please contact us if there are further questions or if additional information is needed.

Sincerely,

(b) (6)

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

cc:

Jesse Mager, IACUC Chair

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: Vice Chancellor for Research and Engagement <vcre@umass.edu>
Sent: Friday, August 19, 2022 11:28 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Vice Chancellor for Research and Engagement; Jesse Mager; (b) (6)
Subject: [EXTERNAL] PHS Assurance #D16-00337 (A3551-01)
Attachments: UMass Amherst Report to OLAW_D1600337_A355101_8-19-2022.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Morse,

In accordance with PHS policy, I write to provide you a preliminary report of non-compliance. Please find the attached letter with a summary of events and corrective measures.

Regards,
Mike

Michael F. Malone
Vice Chancellor for Research & Engagement
University of Massachusetts Amherst

(b) (6)

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McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 19, 2022 12:31 PM
To: Vice Chancellor for Research and Engagement
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: PHS Assurance #D16-00337 (A3551-01)

Good afternoon Mike,

Thank you for sending this preliminary report and we look forward to receiving the final report.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Vice Chancellor for Research and Engagement <vcre@umass.edu>
Sent: Friday, August 19, 2022 11:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Cc: Vice Chancellor for Research and Engagement <vcre@umass.edu>; Jesse Mager <jmager@vasci.umass.edu>; (b) (6)
Subject: [EXTERNAL] PHS Assurance #D16-00337 (A3551-01)

Dear Dr. Morse,

In accordance with PHS policy, I write to provide you a preliminary report of non-compliance. Please find the attached letter with a summary of events and corrective measures.

Regards,
Mike

Michael F. Malone
Vice Chancellor for Research & Engagement
University of Massachusetts Amherst

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