



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

February 24, 2023

Re: Animal Welfare Assurance
A3431-01 [OLAW Case 9Q]

Dr. Lisa Muto
Executive Dean for Administration
Harvard Medical School
25 Shattuck Street, Gordon Hall – (b) (4)
Boston, MA 02115

Dear Dr. Muto,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 14, 2023 letter reporting two related incidents of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals involving the animal care and use program at Harvard Medical School. According to the information provided, OLAW understands that on December 7, 2022, a postdoctoral researcher performed surgery on a cohort of weanling mice in accordance with the protocol but without having completed a mandatory Rodent Surgery course. It was also observed that the post-surgical cards were not completed correctly. The post-surgical cards were corrected immediately, and the lab member has since completed both the online and instructor-led components of the Rodent Surgery course. In addition, between December 14, and December 15, 2022, a cohort of mice aged 21-23 days belonging to the same research group underwent surgery. The use of animals in this age range was not approved on the protocol. The amendment to the animal protocol to clarify and justify the additional age was subsequently approved by the IACUC. The Principal Investigator was notified and provided counseling to the postdoctoral researcher. The Principal Investigator has assured the Committee that animal work will only be done according to the approved protocol, including approved amendments. The associated activity is PHS funded.

OLAW agrees with the actions taken by Harvard Medical School regarding these issues. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate the incidents and to prevent recurrence. We appreciate being informed of these matters and find no cause for further action by this office.

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: 2023.02.25 12:33:28 -05'00'

cc: IACUC contact



HARVARD MEDICAL SCHOOL

A3431-9Q

LISA M. MUTO, Ph.D.
EXECUTIVE DEAN FOR ADMINISTRATION
HARVARD MEDICAL SCHOOL
25 SHATTUCK STREET, (b) (4)
BOSTON, MA 02115

February 14, 2023

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

FINAL REPORT

RE: Non-Compliance Report: Assurance: **A3431-01**
Harvard Medical Area Standing Committee on Animals (HMA IACUC)
Species: *Mus musculus* **Grants:** 5P50MH112491-04

Dear Dr. Morse,

This letter serves as a final report on two incidents that were preliminarily reported to OLAW by the Harvard Medical Area Standing Committee on Animals (HMA IACUC) on February 03, 2023.

On December 7, 2022, a postdoctoral researcher performed ICV delivery of siRNA on a cohort of weanling mice in accordance to the protocol but without having completed a mandatory Rodent Surgery course. The individual explained that another postdoctoral researcher who had completed the Rodent Surgery course and was trained on ICV delivery of siRNA was intended to perform the injections but was not available on that day, so this researcher proceeded independently. The postdoctoral researcher's lack of training was discovered when the veterinary staff observed that the post-surgical cards were not completed correctly. The post-surgical cards were corrected immediately and the lab member has since completed both the online and instructor-led components of the Rodent Surgery course.

Between December 14, and December 15, 2022, a cohort of mice aged 21-23 days belonging to the same research group was injected ICV with siRNA by a postdoctoral researcher. This researcher had previously submitted an amendment to the protocol to include p21 mice, as they learned that p30 was not optimal for siRNA blockade, but this amendment had not yet been approved when surgery occurred. At the time of the surgery, the animal protocol had been approved only for ICV injections mice at p4, 30, and 34 days. The amendment to the animal protocol to clarify and justify the additional age was approved by the IACUC on January 10, 2023. The Principal Investigator was notified and provided counseling to the postdoctoral researcher. The Principal Investigator has assured the Committee that animal work will only be done according to the approved protocol, including approved amendments.

The Committee is satisfied with the corrective actions taken by the laboratory staff and considers these incidents to be resolved. Please let us know if any additional information is required at this time.

Sincerely,

(b) (6)

Lisa M. Muto, PhD

Executive Dean for Administration

HMA Institutional Animal Care & Use Committee: Institutional Official

CC: **Gerald B. Pier, PhD**

Chairman, Harvard Medical Area Standing Committee on Animals

Brian F. Corning, DVM, DACLAM

Executive Director of the Harvard Center for Comparative Medicine, Harvard Medical School:
Attending Veterinarian

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 14, 2023 11:37 AM
To: HMS-IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

Good morning,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: HMS-IACUC <iacuc@hms.harvard.edu>
Sent: Tuesday, February 14, 2023 11:15 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Final Report

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