



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 3, 2023

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

Lisa Muto, Ph.D.
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 July 25, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Harvard Medical School. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this office understands that the Harvard Medical School Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure to adhere to the IACUC-approved protocol and institutional policies/procedures. The final report states between June 9-14, 2023, six mice involved in an orthotopic pancreatic tumor cell implantation study were found dead by husbandry technicians. A review of the laboratory's care logs revealed these animals were not being monitored as described in the IACUC-approved protocol nor per the Harvard Center for Comparative Medicine's Guideline for Survival of Tumor-Bearing Animals.

In response to the incident, the Principal Investigator (PI) has agreed to label the Experimental Illness cards in the animal facility with reminders prompting laboratory staff to adhere to the monitoring scheme. Also, the PI has agreed to implement a shared logbook to track each animal's status following tumor implantation. It is understood a veterinarian developed an optimized monitoring plan for all future and current animals on this study with lab members. The report states the PI agreed to pause tumor cell implantation experiments pending an amendment approval through the IACUC.

The IACUC found these corrective actions to be satisfactory and considers these matters resolved. It is noted this study is supported by PHS funding.

Based on its assessment of this explanation, OLAW understands that the Harvard Medical School has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2023.08.03 14:47:47
-04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

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OLAW Case A3431-9T

cc: IACUC Contact



HARVARD MEDICAL SCHOOL

A3431-9T

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

July 25, 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:** 5R01NS122767-02

Dear Dr. Morse,

This letter serves as a final report on an incident that was not preliminarily reported to OLAW by the Harvard Medical Area Standing Committee on Animals (HMA IACUC).

Between June 9, 2023, and June 14, 2023, six animals on an orthotopic pancreatic tumor cell implantation study were found dead by husbandry technicians approximately one month after implantation procedures. Upon reviewing the laboratory's care logs, it was discovered that these animals were not being monitored according to the scheme delineated in the HMA IACUC-approved protocol or the Harvard Center for Comparative Medicine's Guideline for Survival of Tumor-Bearing Animals.

To ensure appropriate monitoring going forward, the PI has agreed to label the Experimental Illness cards in the animal facility with reminders that prompt laboratory staff to adhere to the monitoring scheme, and has agreed to implement a shared logbook to keep track of each animal's status after tumor cell implantation. Additionally, it was felt that an updated monitoring plan would better ensure appropriate monitoring for animal condition. An HCCM veterinarian developed an optimized monitoring plan for all future and current animals on this study with members of the laboratory. The Principal Investigator has agreed and has paused tumor cell implantation experiments pending amendment approval through the IACUC.

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: Friday, July 28, 2023 3:33 PM
To: HMS-IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

Good afternoon,

Thank you for sending us this final report, assigned OLAW case number A3431-9T, 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: Friday, July 28, 2023 1:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Final Report

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