



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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
Faxsimile: (301) 402-7065

July 7, 2022

Re: Animal Welfare Assurance
A3210 [OLAW Case D]

Rebecca Hartley, J.D.
Assistant Vice President
Research Integrity and Assurance
George Mason University
4400 University Drive
Fairfax, VA 22030

Dear Ms, Hartley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 12, 2022, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at George Mason University. According to the information provided, OLAW understands that a technician practiced tail vein injections on an anesthetized mouse using saline, instead of a contrast agent, as approved in the protocol. Although, the animal subsequently died while under anesthesia, the death was determined to be unrelated to the identified Department of Defense supported noncompliance.

The corrective actions consisted of retraining the Principal Investigator (PI) and his technicians on the regulations related to the animal care and use program, including the CITI regulatory training module "Working with the IACUC." The PI also submitted an amendment to include saline to training animals for IACUC review and approval.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V.

Gopee -S

Neera V. Gopee, DVM, PhD, DAACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

Digitally signed by Neera V.
Gopee -S
Date: 2022.07.07 14:08:07
-04'00'

cc: IACUC Chair

**Office of Research Integrity and Assurance**

4400 University Drive, MSN 6D5, Fairfax, Virginia 22030
Phone: 703-993-2268 Fax: 703-993-9590 Website: oria.gmu.edu

May 12, 2022

Dr. Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Morse,

On March 16, 2022, I provided a preliminary report and prompt notification through e-mail about a potential noncompliant incident involving the unexpected death of a training mouse during a procedure that was conducted under anesthesia. This memorandum serves as the final report of the university's investigation into this incident. This incident involved a minor deviation from the protocol procedures and no suspensions of IACUC activity are involved.

Explanation of Incident

On March 15, 2022, an adverse event involving the death of a training mouse under an approved experiment was brought to the attention of the Attending Veterinarian (AV). The Principal Investigator (PI) of the experiment reported that his technician was practicing tail vein injections on a mouse under chemical restraint and used saline for the injection instead of a contrast agent approved to use in the applicable IACUC protocol. Unfortunately, the animal died before recovering from anesthesia. The death of the animal was determined to be an unfortunate event and not directly caused by the noncompliance. The PI self-reported the incident, completed an adverse event report form to the IACUC, and was fully cooperative throughout the investigation.

The adverse event report was shared with the IACUC committee at the full board meeting on April 22, 2022. Based on the information provided, the IACUC felt that there was no intentional harm to the animal or any intention to not observe and be compliant with policy and procedures. The IACUC concluded the incident was a minor deviation from protocol procedures and was a protocol non-compliance incident, and reported its conclusions to me. The IACUC recommended the PI and his technicians be retrained about the regulations of the animal care and use program and to submit an amendment to the experiment to add the administration of saline for the animals used for training. As the Institutional Official, I concur with the IACUC recommendations.

The IACUC determined that this was an isolated incident and not a programmatic failure. The investigator understands that he should have contacted the AV or IACUC office for information regarding the proper method to amend the procedure for the experiment.

Corrective Actions (implemented within 30 days of notification)

1. The PI and his technicians have been retrained about the regulations guiding the animal care and use program. Retraining included the CITI regulatory compliance module, "Working with the IACUC".
2. The PI submitted an amendment and received approval to his experiment to add the administration of saline for the animals used for training.

Involvement of Grants/Contracts

This noncompliance incident does involve a funded grant from the Department of Defense (DoD Award DARPA/ACURO Number D20AC00004). Notification about this incident was made to the sponsor per their instructions/guidelines for reporting.

Should you have any questions regarding this report, please contact me at rhartle1@gmu.edu or

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Sincerely,

Rebecca Hartley Digitally signed by Rebecca Hartley
Date: 2022.05.12 10:27:01 -04'00'

Rebecca Hartley, J.D.
Assistant Vice President
Research Integrity and Assurance
Institutional Official
George Mason University
Assurance # (D16-00133 (A3210-01))

Cc: Dr. Alonso Aguirre, IACUC Chair, George Mason University

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 18, 2022 7:17 AM
To: Rebecca S Hartley
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Thank you for this preliminary report, Ms. Hartley. We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Rebecca S Hartley <rhartle1@gmu.edu>
Sent: Wednesday, March 16, 2022 11:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Compliance Office <iacuc@gmu.edu>; A. Alonso Aguirre <aaguirr3@gmu.edu>; [REDACTED] (b) (6)
Subject: [EXTERNAL] George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Morse:

This is preliminary notification from George Mason University (D16-00133 (A3210-01)) of a non-compliance incident involving the unexpected death of a training mouse during a procedure that was conducted under anesthesia on March 11, 2022. The researcher self-reported the adverse event to the Attending Veterinarian (AV) on March 15.

During the discussion with a technician involved in the experiment, he disclosed to the AV that he was practicing tail vein injections on a mouse under chemical restraint and used saline for the injection instead of a contrast agent approved to use in the applicable IACUC protocol. Unfortunately, the animal died before recovering from anesthesia.

It is the opinion of the AV that the unexpected death of the mouse was due to an adverse effect of anesthesia and not from the use of the unapproved saline injection.

This study is funded by DARPA/ACURO and a preliminary report of the incident will be submitted to the sponsor. Mason's IACUC is scheduled to meet in April and will discuss the incident and determine corrective action. More details as well a complete report will be provided to you once action is taken.

Kind regards,

Rebecca Hartley, J.D.
Assistant Vice President
Research Integrity and Assurance
Institutional Official
George Mason University

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