



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

May 30, 2024

Re: Animal Welfare Assurance  
A3210-01 (OLAW Case G)

Christopher Diteresi, Ph.D.  
Associate Vice President,  
Research Integrity and Assurance  
George Mason University - Fairfax  
4400 University Dr. (b) (4)  
Fairfax, VA 22030

Dear Dr. Diteresi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 21, 2024 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the George Mason University following up on an initial February 21, 2024 notification by email.

According to the information provided, this office understands that the George Mason University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to the conduct of animal activities without prior IACUC review and approval. The final report states on February 13, 2024, the Attending Veterinarian (AV) was informed that mice were used under an approved protocol for a pilot study that had not been previously approved. It is stated that an investigation determined the Principal Investigator (PI) instructed the research staff to perform a series of injections that were aligned with the scope of the project. It is further stated the specific procedures for the injections and the experimental timeline for the pilot study had not been approved by the IACUC. Per the report, the AV's opinion is that appropriate measures were taken to ensure animal welfare was of the highest priority. It is stated there were no reports of animal welfare concerns due to the noncompliance.

The matter was reviewed by the IACUC at the convened meeting on March 15, 2024, and the following corrective measures taken by the PI were approved:

- The PI has submitted an amendment to the protocol that described the procedures that were performed on the animals as well as expanded on the experiments to allow flexibility to the procedures.
- The PI has developed an outline of all approved procedures in the project to allow a more robust pre-review of the project to prevent reoccurrence.
- The PI conducted a meeting with the laboratory group members on the IACUC protocol to discuss each procedure on the protocol and the importance of adhering strictly to the protocol.

It is noted the research project is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the George Mason University 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: 2024.05.30  
10:36:24 -04'00'

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

cc: IACUC Contact

**Office of Research Integrity and Assurance (ORIA)**

IACUC Office, Research Hall (b) (4)  
4400 University Drive (b) (4) Fairfax, Virginia 22030  
(b) (6) Email: iacuc@gmu.edu; Web: oria.gmu.edu

May 21, 2024

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

Dear Dr. Morse,

On February 21, 2024, I provided a preliminary report (OLAW case number A3210-G) and prompt notification through e-mail about a potential noncompliant incident involving the use of mice for a pilot study experiment within a protocol without IACUC approval. This noncompliance incident involved a violation of the approved protocol procedures and no suspension of IACUC activity was involved. This memorandum serves as the final report of the university's investigation into this incident.

**Explanation of Incident**

On February 13, 2024, it was disclosed to the Attending Veterinarian (AV) that mice were used under an approved IACUC protocol for a pilot study that had not previously been approved in the protocol. Upon further investigation into the incident the AV found that the PI had directed the research staff to perform a series of injections that were aligned with the scope of the project, however the specific procedures for the injections and experimental timeline for the pilot study had not yet been amended and approved by the IACUC. This incident involved a deviation from the protocol procedures and the improper use of animals; however, it is the opinion of the AV that appropriate measures were made to ensure the welfare of the animals were of highest priority and there were no reported animal welfare concerns because of the deviation.

A quorum of the IACUC reviewed the available information at a convened meeting on March 15, 2024, and approved corrective actions taken by the PI:

1. The PI has submitted an amendment to the protocol that described the procedures that were performed on the animals as well as expanded on the experiments to allow flexibility to the procedures.
2. The PI has developed an outline of all approved procedures in the project to allow a more robust pre-review of the project to prevent reoccurrence.
3. The PI conducted a meeting with the laboratory group members on the IACUC protocol to discuss each procedure on the protocol and the importance of adhering strictly to the protocol.



**Involvement of Grants/Contracts**

This noncompliance incident does involve funding related to a PHS-funded research project. Per PHS requirement, the PI has been informed that he must work with his grant administrator to determine if any funding related actions must be taken.

George Mason University is committed to ensuring the welfare of all animals used in research complies with the highest standards of ethical responsibilities and appreciates the guidance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me directly at (b) (6)

Sincerely,

DocuSigned by:  
(b) (6)

Associate Vice President  
Research Integrity and Assurance  
Institutional Official  
George Mason University  
Assurance # (D16-00133 (A3210-01))

Cc: Dr. Aarthi Narayanan, IACUC Chair, George Mason University

(b) (6)



**Ware, Teagan (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, May 22, 2024 2:43 PM  
**To:** 'Compliance Office'  
**Cc:** Aarthi Narayanan (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Good afternoon,

Thank you for providing this final report for OLAW case **A3210-G**. We will send an official response soon.

Best,  
Teagan

Teagan Ware, MS, PMP  
Animal Welfare Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [teagan.ware@nih.gov](mailto:teagan.ware@nih.gov)

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**From:** Compliance Office <iacuc@gmu.edu>  
**Sent:** Wednesday, May 22, 2024 1:11 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Aarthi Narayanan <anaraya1@gmu.edu>; (b) (6)  
**Subject:** [EXTERNAL] Re: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Dear Dr. Morse,

Attached is George Mason's University's final report concerning the non-compliance matter that I notified you about in my February 21, 2024 preliminary notification email. Please let me know if you have any questions.

Kind regards,

Christopher DiTeresi, PhD  
Associate Vice President, Research Integrity and Assurance  
Institutional Official  
George Mason University  
Assurance # (D16-00133 (A3210-01))

**Ware, Teagan (NIH/OD) [E]**

**A3210-G**

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, February 22, 2024 7:32 AM  
**To:** Compliance Office  
**Cc:** Christopher A DiTeresi; Aarthi Narayanan; (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Good morning,

Thank you for providing this preliminary report, which has been assigned as OLAW case **A3210-G**. Please reference this case number when providing any updates or the final report for this incident.

Best,  
Teagan

Teagan Ware, MS, PMP  
Animal Welfare Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [teagan.ware@nih.gov](mailto:teagan.ware@nih.gov)

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**From:** Compliance Office <iacuc@gmu.edu>  
**Sent:** Wednesday, February 21, 2024 4:42 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Christopher A DiTeresi <cditeres@gmu.edu>; Aarthi Narayanan <anaraya1@gmu.edu> (b) (6)  
(b) (6)

**Subject:** [EXTERNAL] George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

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

Dear Dr. Morse:

This memorandum serves as prompt notification from George Mason University (D16-00133 (A3210-01)) of a recent noncompliance incident involving the use of mice for a pilot study experiment within a protocol without IACUC approval. It was disclosed to the Attending Veterinarian (AV) that 6 mice were

used under an IACUC approved protocol for what appears to be a pilot study. Although related to the scope of the project, the procedures for the pilot study were not amended into the approved protocol. This incident involves a deviation from the protocol procedures and the improper use of animals; however, it is the opinion of the AV that appropriate measures have been made to care for the animals and that there is not an animal welfare concern at this time. The IACUC office is still gathering information about the incident and the PI has provided a report with details of the procedures.

This study is funded by the NIH, number 1R01MH134389-01, and a report to the sponsor is expected to be submitted. The IACUC is scheduled to meet in March 2023 and will discuss the incident and determine corrective action. More details as well a complete report will be provided once action is taken.

Thank you,

Christopher DiTeresi, PhD  
Associate Vice President, Research Integrity and Assurance  
Institutional Official  
George Mason University  
Assurance # (D16-00133 (A3210-01))

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