



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 10, 2023

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

Michael Laskofski, MBA
Associate Vice President, Research Services
George Mason University - Fairfax
(b) (4) Merten Hall, MSN 4C6
Fairfax, VA 22030

Dear Mr. Laskofski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 28, 2023 memorandum 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 December 2, 2022 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 in a laboratory space that was not approved by the IACUC for animal use. The final report states on November 29, 2022, a technician self-reported to the IACUC Office and Attending Veterinarian (AV) regarding a terminal perfusion procedure performed under an IACUC-approved protocol. It is stated during the procedure, the animal exhibited signs of waking up from isoflurane anesthesia even after confirmation of anesthetic depth. In response, the mouse was immediately re-anesthetized with isoflurane prior to continuing the perfusion and subsequent euthanasia procedures. It is understood in the AV's opinion appropriate actions were taken and this incident was not an animal welfare concern.

Based on follow-up discussion with the AV, it was determined the procedure was performed outside of the vivarium and in a lab space, which was not approved for animal use for this protocol. In response, the IACUC contacted the Principal Investigator (PI) who was aware of the planned procedure but was not aware that the technician was planning to use the lab outside of the vivarium. The PI provided an incident report to the IACUC with self-imposed corrective actions.

The IACUC reviewed the matter at the December 9, 2022 meeting and recommended acceptance of the PI's corrective action plan. On March 10, 2023, the committee was informed all corrective actions were completed to satisfaction and the plan included the following:

- The PI will provide copies of the IACUC protocol to all group members in his lab and require them all to read the protocol. The PI will encourage each lab member to reach out to him and/or official authorities such as the IACUC office and the Attending Veterinarian in case there are any questions.
- Re-education of the laboratory group members on the IACUC protocol in the form of a group meeting and group discussion. The PI will have a group meeting with all personnel currently

listed on the IACUC protocol to discuss each procedure on the protocol and the importance of adhering strictly to the protocol, including room numbers.

- Re-education for the laboratory technicians on performing transcardial perfusions. The laboratory technicians will undergo additional training on performing transcardial perfusion by the PI.
- The PI will file an amendment to the current IACUC protocol to add (b) (4) of the Krasnow Institute to the list of rooms in which the transcardial perfusion can be performed. The IACUC will inspect the room as part of their routine facility inspections.

It is noted that this research is supported by funding from the Department of Human Health Services. 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: 2023.05.10
07:42:26 -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

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

March 28, 2023

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

Dear Dr. Morse,

On December 02, 2022, I provided a preliminary report (OLAW case number A3210-E) and prompt notification through e-mail about a potential noncompliant incident involving the use of an animal for a terminal procedure (perfusion) conducted in the Principal Investigator's (PI) laboratory space which is not an approved space for animal use by the IACUC. 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 were involved.

Explanation of Incident

On November 29, 2022, a technician self-reported to the IACUC office and Attending Veterinarian (AV) that they had performed a perfusion terminal procedure on an animal under their Principal Investigator's (PI) approved IACUC protocol. During the procedure, the animal displayed signs of waking up from isoflurane anesthesia even after ensuring the mouse was deeply anesthetized by toe and tail pinch and testing the eyelid reflex. The animal was immediately re-anesthetized with isoflurane before continuing the perfusion procedure and euthanization. To note, it is the opinion of the AV that appropriate measures were made expeditiously and this is not an animal welfare concern.

After follow-up by the AV, it was noted, however, that the technician mentioned that they used the animal in their lab space outside of the vivarium, which was not an approved space for animal use for this protocol. The IACUC office reached out to the PI further explanation and after discussion, it is believed to have been a one-time occurrence involving miscommunication about the use of animals for terminal procedures. The PI stated that he was aware that the procedure would be performed, but was not aware the technician was planning to use the lab outside of the vivarium. The PI was fully cooperative throughout the investigative process, provided a report to the IACUC of the incident with details of the incident, and included appropriate self-imposed corrective actions to prevent further noncompliance.

A3210-E

A quorum of the IACUC reviewed the available information at a convened meeting on Friday, December 09, 2022 and agreed the incident was a minor deviation from protocol procedures. The IACUC recommended accepting the self-imposed corrective actions that the PI presented to prevent further noncompliance incidents. As the Institutional Official, I concur with the IACUC recommendation.

The following self-imposed corrective actions were and were implemented 30 days from receipt of this letter. The IACUC was informed at a convened meeting of the full committee on March 10, 2023 that all corrective actions were completed to satisfaction.

1. The PI will provide copies of the IACUC protocol to all group members in his lab and require them all to read the protocol. The PI will encourage each lab member to reach out to him and/or official authorities such as the IACUC office and the Attending Veterinarian in case there are any questions.
2. Re-education of the laboratory group members on the IACUC protocol in form of a group meeting and group discussion. The PI will have a group meeting with all personnel currently listed on the IACUC protocol to discuss each procedure on the protocol and the importance of adhering strictly to the protocol, including room numbers.
3. Re-education for the laboratory technicians on performing transcatheter perfusions. The laboratory technicians will undergo additional training on performing transcatheter perfusion by the PI.
4. The PI will file an amendment to the current IACUC protocol to add (b) (4) of the Krasnow Institute to the list of rooms in which the transcatheter perfusion can be performed. The IACUC will inspect the room as part of their routine facility inspections.

Involvement of Grants/Contracts

This noncompliance incident does involve funding from the Department of Health and Human Services (HHS), (HHS Award number PA-20-188). Notification about this incident to the sponsor was made per their instructions/guidelines for reporting by the PI.

Should you have any questions regarding this report, please contact me at mlaskofs@gmu.edu or (b) (6)

Sincerely,

DocuSigned by:

058C8AFCD01C4D3...
Mike Laskofski

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

Cc: Dr. Avrama Blackwell, IACUC Chair, George Mason University

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Wednesday, March 29, 2023 12:25 PM
To: Compliance Office; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Avrama Blackwell; (b) (6)
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance - OLAW Case number A3210-E

Good afternoon,

Thank you for the final report. We will send an official response soon.

J. Tubbs

From: Compliance Office <iacuc@gmu.edu>
Sent: Wednesday, March 29, 2023 12:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>; Avrama Blackwell <kblackw1@gmu.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance - OLAW Case number A3210-E

Dear Dr. Morse,

Attached is George Mason University's final report concerning the non-compliance matter that I notified you about in my December 02, 2022 preliminary notification email.

Kind regards,

Mike Laskofski
Associate Vice President of Research Services
Institutional Official
George Mason University
Assurance # (D16-00133 (A3210-01))

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, December 5, 2022 7:33 AM
To: Compliance Office <iacuc@gmu.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Good morning Mr. Laskofski,

Thank you for sending us this preliminary report and we look forward to receiving the final report once completed. This report has been assigned OLAW case number **A3210-E**, so please reference this number when sending the final report.

Thanks,
Devora

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

From: Compliance Office <iacuc@gmu.edu>

Sent: Friday, December 2, 2022 4:30 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Michael Laskofski <mlaskofs@gmu.edu>; Avrama Blackwell <kblackw1@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 is a preliminary notification from George Mason University (D16-00133 (AS210-01)) of a protocol non-compliance incident involving the use of an animal for a terminal procedure (perfusion) conducted in the Principal Investigator's (PI) laboratory space which is not an approved space for animal use by the IACUC. On November 29, 2022, the PI's technician self-reported that they had performed a perfusion terminal procedure on an animal under their approved IACUC protocol. During the procedure, the animal displayed signs of waking up from isoflurane anesthesia even after ensuring the mouse was deeply anesthetized by toe and tail pinch and testing the eyelid reflex. The technician noticed that the nose cone had momentarily slipped from the animal. The animal was immediately re-anesthetized with isoflurane before continuing the perfusion procedure and euthanization. It is the opinion of the Attending Veterinarian that appropriate measures were made expeditiously and this not an animal welfare concern.

After follow-up by the AV, it was noted that the technician mentioned that they used the animal in their lab space outside of the vivarium which is not an approved space for this protocol. The IACUC office reached out to the PI for further explanation and after discussion, it is believed to have been a one-time occurrence involving miscommunication about the use of animals for terminal procedures. The PI stated that he was aware that the procedure would be done, but was not aware the technician was planning to use their lab outside of the vivarium. The PI was out of town at the time and was not available to possibly prevent the occurrence had he known. The IACUC office is still gathering more information of the incident and is expecting the PI to provide a report with details of the incident.

This study is funded by the Department of Health and Human Services (HHS), number PA-20-188, and a report to the sponsor is expected to be submitted. The IACUC is scheduled to meet on December 9, 2022 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,

Mike Laskofski
Associate Vice President of Research Services
Institutional Official
George Mason University
Assurance # (D16-00133 (A3210-01))

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.

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.

Tubbs, Jai (NIH/OD) [E]

From: Compliance Office <iacuc@gmu.edu>
Sent: Tuesday, March 28, 2023 2:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Tubbs, Jai (NIH/OD) [E]
Subject: [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Good afternoon,

Thank you for your follow up inquiry. This incident has been recently resolved and we have drafted the finalized report for the IO to sign and submit. I will bring this to his attention and have it submitted to close this case as soon as possible.

Best regards,

===== (b) (6)



From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, March 28, 2023 2:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Compliance Office <iacuc@gmu.edu>
Cc: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Hello,

I am following up on case number A3210-E regarding an incident report in December 2022. Please let me know the status of the final report and when submission to OLAW can be expected.

Kind Regards,

J. Tubbs

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, December 5, 2022 7:33 AM
To: Compliance Office <iacuc@gmu.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 28, 2023 2:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD); Compliance Office
Cc: Tubbs, Jai (NIH/OD) [E]
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Hello,

I am following up on case number A3210-E regarding an incident report in December 2022. Please let me know the status of the final report and when submission to OLAW can be expected.

Kind Regards,

J. Tubbs

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, December 5, 2022 7:33 AM
To: Compliance Office <iacuc@gmu.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Preliminary Notification of Non-Compliance

Good morning Mr. Laskofski,

Thank you for sending us this preliminary report and we look forward to receiving the final report once completed. This report has been assigned OLAW case number **A3210-E**, so please reference this number when sending the final report.

Thanks,
Devora

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

From: Compliance Office <iacuc@gmu.edu>
Sent: Friday, December 2, 2022 4:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Michael Laskofski <mlaskofs@gmu.edu>; Avrama Blackwell <kblackw1@gmu.edu>; (b) (6)

A3210-E

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 5, 2022 7:33 AM
To: Compliance Office
Cc: 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 Mr. Laskofski,

Thank you for sending us this preliminary report and we look forward to receiving the final report once completed. This report has been assigned OLAW case number **A3210-E**, so please reference this number when sending the final report.

Thanks,
Devora

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

From: Compliance Office <iacuc@gmu.edu>
Sent: Friday, December 2, 2022 4:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Michael Laskofski <mlaskofs@gmu.edu>; Avrama Blackwell <kblackw1@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 is a preliminary notification from George Mason University (D16-00133 (AS210-01)) of a protocol non-compliance incident involving the use of an animal for a terminal procedure (perfusion) conducted in the Principal Investigator's (PI) laboratory space which is not an approved space for animal use by the IACUC. On November 29, 2022, the PI's technician self-reported that they had performed a perfusion terminal procedure on an animal under their approved IACUC protocol. During the procedure, the animal displayed signs of waking up from isoflurane anesthesia even after ensuring the mouse was deeply anesthetized by toe and tail pinch and testing the eyelid reflex. The technician noticed that the nose cone had momentarily slipped from the animal. The animal was immediately re-anesthetized with isoflurane before continuing the perfusion procedure and euthanization. It is the opinion of the Attending Veterinarian that appropriate measures were made expeditiously and this not an animal welfare concern.

After follow-up by the AV, it was noted that the technician mentioned that they used the animal in their lab space outside of the vivarium which is not an approved space for this protocol. The IACUC office reached out to the PI for further explanation and after discussion, it is believed to have been a one-time occurrence involving miscommunication about the use of animals for terminal procedures. The PI stated that he was aware that the procedure would be done, but was not aware the technician was planning to use their lab outside of the vivarium. The PI was out of town at the time and was not available to possibly prevent the occurrence had he known. The IACUC office is still gathering more information of the incident and is expecting the PI to provide a report with details of the incident.

This study is funded by the Department of Health and Human Services (HHS), number PA-20-188, and a report to the sponsor is expected to be submitted. The IACUC is scheduled to meet on December 9, 2022 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,

Mike Laskofski
Associate Vice President of Research Services
Institutional Official
George Mason University
Assurance # (D16-00133 (A3210-01))

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.
