

A3210-F



**Office of Research Integrity and Assurance**

4400 University Drive, MSN 6D5, Fairfax, Virginia 22030  
Phone: 703-993-6118 Fax: 703-993-9590 Website: [oria.gmu.edu](http://oria.gmu.edu)

April 27, 2023

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

OLAW Case Number A3210-F

Dear Dr. Morse,

This memorandum serves as the final report from George Mason University (D16-00133) on the status of the OLAW case number A3210-F. Earlier this month, the Principal Investigator (PI) of IACUC protocol 0420 complied and completed the corrective actions directed by the IACUC committee as terms for reinstatement. During the April 2023 IACUC meeting held earlier this month, the committee reviewed the actions, voted unanimously to reinstate the protocol back to good standing, and lifted the suspension. This concludes the university's investigation in this incident.

**Explanation of Incident**

On November 17, 2022, it was brought to the attention of the IACUC office that expired bottles of analgesics and antibiotics (Ketoprofen - expiration date of 12/2020; Gentamycin Sulfate Solution - expiration of 10/2020) were found in one of the procedure rooms in the animal facility by the Animal Facility Supervisor. The PI's drugs are routinely stored in their non-animal use lab spaces outside of the vivarium, which prevented the IACUC from discovering the problem earlier during routine inspections. Upon discovery, the Animal Facility Supervisor questioned the technician if the expired drugs were used to administer injections during a survival surgery that was performed that day in which the technician suggested they had been used. Upon confirmation, the Animal Facility Supervisor encouraged the technician to contact their Principal Investigator (PI) and report the incident to the AV and the IACUC.

The following day, the PI acknowledged in email that they indeed have been using expired drugs in the survival surgeries and recovery periods and that he will be investigating the issue in his lab and provide a report to the IACUC. The report was received on November 22, 2022 and provided additional information from the PI that explained that the expired drugs were used during thirteen survival surgeries and recoveries since July 2022. Immediate remediation included procuring new stock of unexpired drugs and disposal of those that had expired. The AV also performed wellness checks on the animals and in her opinion, did not believe the animals to be in pain or distress that required further

veterinary action. There were also no reported veterinary cases for the animals were used in past surgeries.

The noncompliance report was shared with the IACUC committee at a specially convened full board meeting on November 29, 2022. Based on the information provided, the IACUC felt that while PI may not have had the intention to use expired drugs, it was concerning that the PI is not providing adequate oversight of the animals and their use on this protocol. The severity in which these incidents of improper oversight of care and use to our most vulnerable animals who undergo survival surgery procedures is a serious deviation from Mason policies and Assurance, PHS Policy, and The Guide. The IACUC agreed the reported incidents are serious deviations from protocol procedures and reported them to me along with their recommendations for corrective actions. As the Institutional Official, I concur to the IACUC requested corrective actions as outlined below.

The IACUC reviewed the available information and recommend the following corrective actions:

1. Immediate suspension of all animal activities on IACUC protocol 0420 for 60 days or more, conditional on completing all required corrective actions. Reinstatement of activities under 0420 may be lifted sooner than 60 days if conditions of follow up actions are completed/corrected at the discretion of the IACUC committee. The IACUC committee will review all criteria at a convened meeting before approval of reinstatement will be granted.
2. The PI and his personnel listed on IACUC protocol 0420 must be retrained about the regulations guiding the animal care and use program. Retraining must include:
  - a. CITI regulatory compliance modules: Working with the IACUC; Reducing Pain and Distress in Laboratory Mice and Rats; Working with Rats in Research Settings; & Aseptic Surgery.
  - b. Review of IACUC policies and facility-specific SOPs
3. The PI and his personnel listed on IACUC protocol 0420 must be retrained in surgical procedures and proper documentation practices with the Attending Veterinarian.
4. A full, in-depth Post Approval Monitoring (PAM) audit of protocol 0420 must be conducted by a sub-committee of the IACUC committee. The purpose of the audit is to ensure research and teaching activities involving live, vertebrate animals are conducted with all applicable federal and state laws, accrediting body regulations, University policies, and are consistent with the PI's IACUC approved protocol and amendments.
5. To help facilitate compliance as our animal user in the animal care and use program, the IACUC will conduct an inspection of all of the PI's laboratory spaces outside of the vivarium and continuing at least semi-annually (or more) as part of the routine inspection schedules.
6. The PI must develop a lab-specific Standard Operating Procedure (SOP) addressing drug storage and monitoring. The SOP should include procedures to monitor drug stock, eliminate expired drugs, proper labeling and documentation, etc.

**Involvement of Grants/Contracts**

This noncompliance incident does not currently involve funded grant from PHS, HHS, NASA, or NSF. However, institutional funds were used in support of the IACUC protocol, but the work was related to an NIH award 1R15AG045820 that expired on August 31, 2022.

Should you have any questions regarding this report, please contact me at [mlaskofs@gmu.edu](mailto:mlaskofs@gmu.edu) or

(b) (6)

Sincerely,

(b) (6)

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

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

(b) (6)

## McCoy, Devora (NIH/OD) [E]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 28, 2023 12:53 PM  
**To:** Compliance Office  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity - OLAW Case number A3210-F

Good afternoon Mr. Laskofski,

Thank you for sending us this final report for case A3210-F 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](mailto:devora.mccoy@nih.gov)

---

**From:** Compliance Office <[iacuc@gmu.edu](mailto:iacuc@gmu.edu)>  
**Sent:** Friday, April 28, 2023 11:56 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** Tubbs, Jai (NIH/OD) [E] <[jacquelyn.tubbs@nih.gov](mailto:jacquelyn.tubbs@nih.gov)>; Avrama Blackwell <[kblackw1@gmu.edu](mailto:kblackw1@gmu.edu)>; (b) (6)  
(b) (6)  
**Subject:** [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity - OLAW Case number A3210-F

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 and in my March 30, 2023 interim report email.

Kind regards,

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

**From:** Compliance Office

**Sent:** Thursday, March 30, 2023 11:58 AM

**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)

**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity - OLAW Case number A3210-F

Dear Dr. Morse,

Attached is George Mason University's interim report concerning the non-compliance matter that I notified you about in my December 02, 2022 preliminary notification email. The status of the case is still pending resolution, but is anticipated to be resolved in April. I will send a final report as soon as it is resolved.

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)) Notice of Suspension of Animal Activity

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-F**, 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 4:38 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)) Notice of Suspension of Animal Activity

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) describing a recent noncompliance incident involving the use of expired drugs during survival surgery and recovery in rats under an IACUC-approved protocol. This incident involved a deviation from the protocol procedures and the suspension of IACUC activity under this protocol are involved. Institutional funds were used in support of the IACUC protocol, but the work was related to an NIH award 1R15AG045820 that expired on August 31, 2022. A finalized report of corrective actions will be sent for your records detailing the result of corrective actions made for project reinstatement.

Thank you,  
Mike Laskofski  
Associate Vice President of Research Services  
Institutional Official  
George Mason University  
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A3210-F



**Office of Research Integrity and Assurance**

4400 University Drive, MSN 6D5, Fairfax, Virginia 22030  
Phone: 703-993-6118 Fax: 703-993-9590 Website: [oria.gmu.edu](http://oria.gmu.edu)

March 29, 2023

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

OLAW Case Number A3210-F

Dear Dr. Morse,

This memorandum serves as an interim report from George Mason University (D16-00133) on the status of the OLAW case number A3210-F. The suspension of IACUC protocol 0420 is still in place as of this memo because the Principal Investigator (PI) has not yet completed all of the corrective actions presented to him by our IACUC. The reason of the delay is due in part to personal and professional conflicts of the PI in recent months to provide a timely completion of the corrective actions. My office is working cooperatively with the PI to expedite the completion of the corrective actions and is expected to be finalized at the next scheduled IACUC in April 2023. As soon as the IACUC reinstates the protocol to good standing, I will send the final report for your records.

**Explanation of Incident**

On November 17, 2022, it was brought to the attention of the IACUC office that expired bottles of analgesics and antibiotics (Ketoprofen - expiration date of 12/2020; Gentamycin Sulfate Solution - expiration of 10/2020) were found in one of the procedure rooms in the animal facility by the Animal Facility Supervisor. The Principal Investigator's (PI) drugs are routinely stored in their non-animal use lab spaces outside of the vivarium, which prevented the IACUC from discovering the problem earlier during routine inspections. Upon discovery, the Animal Facility Supervisor questioned the technician if the expired drugs were used to administer injections during a survival surgery that was performed that day in which the technician suggested they had been used. Upon confirmation, the Animal Facility Supervisor encouraged the technician to contact their Principal Investigator (PI) and report the incident to the AV and the IACUC.

The following day, the PI acknowledged in email that they indeed have been using expired drugs in the survival surgeries and recovery periods and that he will be investigating the issue in his lab and provide a report to the IACUC. The report was received on November 22, 2022 and provided additional information from the PI that explained that the expired drugs were used during thirteen survival surgeries and recoveries since July 2022. Immediate remediation included procuring new stock of

unexpired drugs and disposal of those that had expired. The AV also performed wellness checks on the animals and in her opinion, did not believe the animals to be in pain or distress that required further veterinary action. There were also no reported veterinary cases for the animals were used in past surgeries.

The noncompliance report was shared with the IACUC committee at a specially convened full board meeting on November 29, 2022. Based on the information provided, the IACUC felt that while PI may not have had the intention to use expired drugs, it was concerning that the PI is not providing adequate oversight of the animals and their use on this protocol. The severity in which these incidents of improper oversight of care and use to our most vulnerable animals who undergo survival surgery procedures is a serious deviation from Mason policies and Assurance, PHS Policy, and The Guide. The IACUC agreed the reported incidents are serious deviations from protocol procedures and reported them to me along with their recommendations for corrective actions. As the Institutional Official, I concur to the IACUC requested corrective actions as outlined below.

The IACUC reviewed the available information and recommend the following corrective actions:

1. Immediate suspension of all animal activities on IACUC protocol 0420 for 60 days or more, conditional on completing all required corrective actions. Reinstatement of activities under 0420 may be lifted sooner than 60 days if conditions of follow up actions are completed/corrected at the discretion of the IACUC committee. The IACUC committee will review all criteria at a convened meeting before approval of reinstatement will be granted.
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Should you have any questions regarding this report, please contact me at [mlaskofs@gmu.edu](mailto:mlaskofs@gmu.edu) or

(b) (6)

Sincerely,

(b) (6)

Mike Laskotski

Associate Vice President of Research Services

Institutional Official

George Mason University

Assurance # (D16-00133 (A3210-01))

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

(b) (6)

**McCoy, Devora (NIH/OD) [E]**

---

**From:** Tubbs, Jai (NIH/OD) [E]  
**Sent:** Thursday, March 30, 2023 12:26 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)) Notice of Suspension of Animal Activity - OLAW Case number A3210-F

Hello,

Thank you for the interim report. We will add it to the case file while we await receipt of the final report.

Kind Regards,

J. Tubbs

**From:** Compliance Office <iacuc@gmu.edu>  
**Sent:** Thursday, March 30, 2023 11:58 AM  
**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)  
**Subject:** [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity - OLAW Case number A3210-F

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Kind regards,

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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)) Notice of Suspension of Animal Activity

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-F**, 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 4:38 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)

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**Subject:** [EXTERNAL] George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity

Dr. Brent Morse, DVM  
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National Institutes of Health

Dear Dr. Morse:

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Thank you,  
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Institutional Official  
George Mason University  
Assurance # (D16-00133 (A3210-01))

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**Tubbs, Jai (NIH/OD) [E]**

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**From:** Compliance Office <iacuc@gmu.edu>  
**Sent:** Tuesday, March 28, 2023 2:48 PM  
**To:** Tubbs, Jai (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity

We will have this sent as soon as possible.

Thank you!

=====  
 (b) (6)

---

**From:** Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>  
**Sent:** Tuesday, March 28, 2023 2:44 PM  
**To:** Compliance Office <iacuc@gmu.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity

Hello,

Yes, an interim report would be appreciated regarding this case.

Thank you,

J. Tubbs

---

**From:** Compliance Office <iacuc@gmu.edu>  
**Sent:** Tuesday, March 28, 2023 2:35 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>  
**Subject:** [EXTERNAL] RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity

Good afternoon,

Thank you for the follow up inquiry. Unfortunately, this case has still yet to be resolved fully. The PI has not yet completed all of the corrective actions presented to him by our IACUC and the study is still suspended. Would an updated report on where we are in the process of reinstatement help to update the file for this case? If not, we are hoping that we can continue to work with the PI to complete the necessary corrective actions for the IACUC to review for protocol reinstatement within the next few weeks.

**Tubbs, Jai (NIH/OD) [E]**

---

**From:** Tubbs, Jai (NIH/OD) [E]  
**Sent:** Tuesday, March 28, 2023 2:44 PM  
**To:** Compliance Office; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: George Mason University (Assurance Number: D16-00133 (A3210-01)) Notice of Suspension of Animal Activity

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Best regards,

(b) (6)



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**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Tuesday, March 28, 2023 2:04 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)) Notice of Suspension of Animal Activity

**Tubbs, Jai (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, March 28, 2023 2:04 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)) Notice of Suspension of Animal Activity

Hello again,

Please let me know the status of the final report for A3210-F, and when submission of the report can be expected for review.

Kind Regards,

J. Tubbs

---

**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Monday, December 5, 2022 7:33 AM  
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Thanks,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
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(b) (6)

A3210-F



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December 02, 2022

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

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On November 17, 2022, it was brought to the attention of the IACUC office that expired bottles of analgesics and antibiotics (Ketoprofen - expiration date of 12/2020; Gentamycin Sulfate Solution - expiration of 10/2020) were found in one of the procedure rooms in the animal facility by the Animal Facility Supervisor. The Principal Investigator's (PI) drugs are routinely stored in their non-animal use lab spaces outside of the vivarium, which prevented the IACUC from discovering the problem earlier during routine inspections. Upon discovery, the Animal Facility Supervisor questioned the technician if the expired drugs were used to administer injections during a survival surgery that was performed that day in which the technician suggested they had been used. Upon confirmation, the Animal Facility Supervisor encouraged the technician to contact their Principal Investigator (PI) and report the incident to the AV and the IACUC.

The following day, the PI acknowledged in email that they indeed have been using expired drugs in the survival surgeries and recovery periods and that he will be investigating the issue in his lab and provide a report to the IACUC. The report was received on November 22, 2022 and provided additional information from the PI that explained that the expired drugs were used during thirteen survival surgeries and recoveries since July 2022. Immediate remediation included procuring new stock of unexpired drugs and disposal of those that had expired. The AV also performed wellness checks on the animals and in her opinion, did not believe the animals to be in pain or distress that required further veterinary action. There were also no reported veterinary cases for the animals were used in past surgeries.

The noncompliance report was shared with the IACUC committee at a specially convened full board meeting on November 29, 2022. Based on the information provided, the IACUC felt that while PI may not have had the intention to use expired drugs, it was concerning that the PI is not providing adequate oversight of the animals and their use on this protocol. The severity in which these incidents of improper oversight of care and use to our most vulnerable animals who undergo survival surgery procedures is a serious deviation from Mason policies and Assurance, PHS Policy, and The Guide. The IACUC agreed the reported incidents are serious deviations from protocol procedures and reported them to me along with their recommendations for corrective actions. As the Institutional Official, I concur to the IACUC requested corrective actions as outlined below.

The IACUC reviewed the available information and recommend the following corrective actions:

1. Immediate suspension of all animal activities on IACUC protocol 0420 for 60 days or more, conditional on completing all required corrective actions. Reinstatement of activities under 0420 may be lifted sooner than 60 days if conditions of follow up actions are completed/corrected at the discretion of the IACUC committee. The IACUC committee will review all criteria at a convened meeting before approval of reinstatement will be granted.
2. The PI and his personnel listed on IACUC protocol 0420 must be retrained about the regulations guiding the animal care and use program. Retraining must include:
  - a. CITI regulatory compliance modules: Working with the IACUC; Reducing Pain and Distress in Laboratory Mice and Rats; Working with Rats in Research Settings; & Aseptic Surgery.
  - b. Review of IACUC policies and facility-specific SOPs
3. The PI and his personnel listed on IACUC protocol 0420 must be retrained in surgical procedures and proper documentation practices with the Attending Veterinarian.
4. A full, in-depth Post Approval Monitoring (PAM) audit of protocol 0420 must be conducted by a sub-committee of the IACUC committee. The purpose of the audit is to ensure research and teaching activities involving live, vertebrate animals are conducted with all applicable federal and state laws, accrediting body regulations, University policies, and are consistent with the PI's IACUC approved protocol and amendments.
5. To help facilitate compliance as our animal user in the animal care and use program, the IACUC will conduct an inspection of all of the PI's laboratory spaces outside of the vivarium and continuing at least semi-annually (or more) as part of the routine inspection schedules.
6. The PI must develop a lab-specific Standard Operating Procedure (SOP) addressing drug storage and monitoring. The SOP should include procedures to monitor drug stock, eliminate expired drugs, proper labeling and documentation, etc.



**Involvement of Grants/Contracts**

This noncompliance incident does not currently involve funded grant from PHS, HHS, NASA, or NSF. However, institutional funds were used in support of the IACUC protocol, but the work was related to an NIH award 1R15AG045820 that expired on August 31, 2022.

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

Sincerely,

(b) (6)

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

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

(b) (6)

**McCoy, Devora (NIH/OD) [E]**

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**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)) Notice of Suspension of Animal Activity

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-F**, 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 4:38 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)) Notice of Suspension of Animal Activity

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) describing a recent noncompliance incident involving the use of expired drugs during survival surgery and recovery in rats under an IACUC-approved protocol. This incident involved a deviation from the protocol procedures and the suspension of IACUC activity under this protocol are involved. Institutional funds were used in support of the IACUC protocol, but the work was related to an NIH award 1R15AG045820 that expired on August 31, 2022. A finalized report of corrective actions will be sent for your records detailing the result of corrective actions made for project reinstatement.

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.



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 11, 2023

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

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 April 27, 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 suspension of a protocol pending completion of all corrective actions regarding a noncompliance. The interim report (dated March 29, 2023) stated the incident occurred on November 17, 2022, when the IACUC office was notified that expired bottles of analgesics and antibiotics were identified in a procedure room in the animal facility by the Animal Facility Supervisor. The supervisor questioned the technician, asking if the expired drugs were used to administer injections during a survival surgery that was performed that day. Ultimately, it was determined the lab had been administering the expired drugs in survival surgeries and recovery periods and the Principal Investigator (PI) would investigate the issue within his lab and provide a report to the IACUC.

The IACUC received the PI's report on November 22, 2022 and explained the expired drugs were administered during 13 survival surgeries and recoveries since July 2022. It is understood immediate remediation involved procurement of new stock of unexpired drugs and disposal of expired drugs. The Attending Veterinarian performed wellness checks on animals and determined the animals were not in pain/distress nor did they require further veterinary action. The incident was discussed by the IACUC on November 29, 2022 and the committee requested corrective actions of the PI as described in the interim report. One action was the immediate suspension of all animal activities pending completion of all required corrective actions.

The final report states the PI has completed the corrective actions as directed by the IACUC as terms of reinstatement of the protocol. The complete corrective action plan included the following:

- Immediate suspension of all animal activities on IACUC protocol 0420 for 60 days or more, conditional on completing all required corrective actions. Reinstatement of activities under 0420 may be lifted sooner than 60 days if conditions of follow up actions are completed/corrected at the discretion of the IACUC committee. The IACUC will review all criteria at a convened meeting before approval of reinstatement will be granted.

- The PI and his personnel listed on IACUC protocol 0420 must be retrained about the regulations guiding the animal care and use program. Retraining must include:
  - CITI regulatory compliance modules: Working with the IACUC; Reducing Pain and Distress in Laboratory Mice and Rats; Working with Rats in Research Settings; & Aseptic Surgery.
  - Review of IACUC policies and facility-specific Standard Operating Procedure (SOPs).
- The PI and his personnel listed on IACUC protocol 0420 must be retrained in surgical procedures and proper documentation practices with the Attending Veterinarian.
- A full, in-depth Post Approval Monitoring (PAM) audit of protocol 0420 must be conducted by a subcommittee of the IACUC. The purpose of the audit is to ensure research and teaching activities involving live, vertebrate animals are conducted with all applicable federal and state laws, accrediting body regulations, University policies, and are consistent with the PI's IACUC approved protocol and amendments.
- To help facilitate compliance as our animal user in the animal care and use program, the IACUC will conduct an inspection of all the PI's laboratory spaces outside of the vivarium and continuing at least semi-annually (or more) as part of the routine inspection schedules.
- The PI must develop a lab-specific SOP addressing drug storage and monitoring. The SOP should include procedures to monitor drug stock, eliminate expired drugs, proper labeling, and documentation, etc.

It is noted that institutional funds were used in support of the IACUC protocol, but the work was related to an NIH award that expired on August 31, 2022. 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 Tubbs, DVM, DAACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact