



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
Bethesda, Maryland 20892-7982
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

November 12, 2020

Re: Animal Welfare Assurance
A3307-01 [OLAW Case Y]

Dr. Michael Diamond
Senior Vice President for Research Administration
Augusta University
1120 Fifteen Street
Augusta, GA 30912

Dear Dr. Diamond,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 3, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University. Your letter supplements the information contained in your October 23rd emailed prompt, preliminary report. According to the information provided, OLAW understands that on the morning of October 22, 2020 you received an incident report that surgery was performed on two mice on October 20th. The person who did the surgery left work without waiting for the animals to recover or arranging for monitoring of the animal. The mice were found on the morning of October 21st in a cage without water or bedding. This was the third incident report for this PI in three months. The PI is NIH-funded.

Corrective and preventive measures included retraining of the PI and her staff in rodent aseptic survival surgery with an emphasis on monitoring and recovery. Surgeries were suspended until training was completed. The IACUC Chair provided a presentation on animal welfare and compliance and went through the protocol with the lab staff. The PI has identified a senior member of her laboratory as the primary point of contact for LAS. A fine has been paid by the PI from a non-NIH source.

The prompt consideration of this matter by Augusta University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. **Please note** it is apparent that the August 3, 2020 and the September 28, 2020 incidents of unapproved tail snips in mice should have been promptly reported to our office. Please be sure to contact OLAW if questions arise as to the reportability of an incident. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



AUGUSTA
UNIVERSITY

Medical College of Georgia
Department of Physiology
1120 15th Street, CA-3124
Augusta, GA 30912

November 3rd, 2020

Michael P. Diamond, M.D., Institutional Official
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research

Dear Dr. Diamond:

This letter is a follow up to a preliminary report of repeated non-compliance by the laboratory of a PHS funded member of faculty submitted to OLAW on October 23rd, 2020.

- On the morning of October 22nd we received an incident report that surgery was performed on two mice on October 20th. The person who did the surgery left work without waiting for the animals to recover or arranging for monitoring of the animals as they recovered. The mice were found by LAS staff on the morning of October 21st in a cage without water or bedding.
- This was the third incident report for this PI in three months (August 3rd, September 28th and October 22nd). The first report was that LAS staff found two cages containing a total of 8 adult mice that had blood on the bedding and Nestlets due to tail snip. The mice were healthy but the PI did not have approval for tail snip of mice older than 20 days. The PI was told to stop performing this procedure and submit an amendment to her AUP. The second report was that a cage containing 3 adult mice had blood on the bedding following tail snip. At this time an amendment had been submitted, but not approved. The PI and staff were told not to perform this procedure until the amendment was approved and also received training on the appropriate methods for tail snip of adult mice.
- The two most recent incidents and the issue of recurring non-compliance were discussed at the IACUC meeting on October 22nd and the committee recommended the following responses:
 - The PI and her staff refrain from performing any surgery until everyone named on the PI's AUP receives training in rodent aseptic survival surgery with an emphasis on monitoring and recovery. *This training was completed on November 2nd, 2020 and the laboratory has resumed surgery.*
 - In the absence of any scheduled OLAW IACUC 101 workshops that the IACUC Chair meet with the members of the laboratory to provide training on responsible conduct of animal research and to review the PI's Animal Use Protocol (AUP). *The IACUC Chair provided a presentation on animal welfare and compliance and went through the PI's AUP in a socially distanced meeting on October 27th, 2020.*
 - Because there are a large number of staff in the laboratory, that the PI identify an individual who takes responsibility for ensuring compliance and serves as the primary contact for LAS. *The PI has identified a senior member of her laboratory as the primary*

Phone 706-721-4479 Fax 706-721-7299 <https://www.augusta.edu/mcg/phy/>
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contact.

- o If the IACUC receives another incident report, then the committee will consider suspending the PI's AUP. *This information was provided to the PI in an email sent on October 23rd, 2020.*
- o That the PI be fined \$5,000, paid from a non-NIH fund. *These funds were transferred to the IACUC account on October 30th, 2020.*

For reporting purposes, our Assurance Number (A3307-01) is provided.

Submitted on behalf of the IACUC.

(b) (6)

Ruth Harris, PhD
Regents Professor

Report received and approved by the Institutional Official.

(b) (6)

11/3/2020

Michael P. Diamond, M.D., Institutional Official
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 4, 2020 7:17 AM
To: SVPRESEARCH
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Augusta University follow up to Incident Report - A3307-01

Thank you for this report, Dr. Diamond. We will send a response soon.

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

From: SVPRESEARCH <SVPRESEARCH@augusta.edu>
Sent: Tuesday, November 3, 2020 6:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Diamond, Michael <michael.diamond@augusta.edu>; (b) (6) Harris, Ruth <RUHARRIS@augusta.edu>
Subject: Augusta University follow up to Incident Report - A3307-01

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached is a letter to follow up to a preliminary report of repeated non-compliance by the laboratory of a PHS funded member of faculty submitted to OLAW on October 23rd, 2020. If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,

Michael P. Diamond, MD

Institutional Official

Senior Vice President for Research

Augusta University



AUGUSTA
UNIVERSITY

Medical College of Georgia
Department of Physiology
1120 15th Street, CA-3124
Augusta, GA 30912

October 23rd, 2020

Michael P. Diamond, M.D., Institutional Official
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research

Dear Dr. Diamond:

This letter the preliminary report of repeated non-compliance by the laboratory of a PHS funded member of faculty.

- On the morning of October 22nd we received an incident report that surgery was performed on two mice on October 20th. The person who did the surgery left work without waiting for the animals to recover or arranging for monitoring of the animals as they recovered. The mice were found by LAS staff on the morning of October 21st in a cage without water or bedding.
- This was the third incident report for this PI in three months (August 3rd, September 28th and October 22nd). The first report was that LAS staff found two cages containing a total of 8 adult mice that had blood on the bedding and Nestlets due to tail snip. The mice were healthy but the PI did not have approval for tail snip of mice older than 20 days. The PI was told to stop performing this procedure and submit an amendment to her AUP. The second report was that a cage containing 3 adult mice had blood on the bedding following tail snip. At this time an amendment had been submitted, but not approved. The PI and staff were told not to perform this procedure until the amendment was approved and also received training on the appropriate methods for tail snip of adult mice.
- The two most recent incidents and the issue of recurring non-compliance were discussed at the IACUC meeting on October 22nd and the committee recommended the following responses:
 - The PI and her staff refrain from performing any surgery until everyone named on the PI's AUP receives training in rodent aseptic survival surgery with an emphasis on monitoring and recovery.
 - In the absence of any scheduled OLAW IACUC 101 workshops that the IACUC Chair meet with the members of the laboratory to provide training on responsible conduct of animal research and to review the PI's Animal Use Protocol (AUP)
 - Because there are a large number of staff in the laboratory, that the PI identify an individual who takes responsibility for ensuring compliance and serves as the primary contact for LAS.
 - If the IACUC receives another incident report, then the committee will consider suspending the PI's AUP
 - That the PI be fined \$5,000, paid from a non-NIH fund
- The PI was informed of these decisions by email on October 23rd.

For reporting purposes, our Assurance Number (A3307-01) is provided.

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Submitted on behalf of the IACUC,

(b) (6)

Ruth Harris, PhD
Regents Professor

Report received and approved by the Institutional Official,

(b) (6)

10/23/2020

Michael P. Diamond, M.D., Institutional Official
Professor of Obstetrics and Gynecology
Leon Henri Charbonnier Endowed Chair
Associate Dean for Research, Medical College of Georgia
Senior Vice President for Research

Walker, Keri (NIH/OD) [C]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Sunday, October 25, 2020 8:25 PM
To: Walker, Keri (NIH/OD) [C]
Subject: FW: Augusta University reportable incident_10232020 - A3307-01

Keri, please use this email to open a new case file. Assign this to me. Thank you. Brent

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

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Sunday, October 25, 2020 8:24 PM
To: SVPRESEARCH <SVPRESEARCH@augusta.edu>
Cc: (b) (6) Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Augusta University reportable incident_10232020 - A3307-01

Thank you for providing this preliminary report. We will open a case file and await further information.

Best regards, Brent Morse

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

From: SVPRESEARCH <SVPRESEARCH@augusta.edu>
Sent: Friday, October 23, 2020 7:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>
Subject: Augusta University reportable incident_10232020 - A3307-01

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached is a letter to provide information on a preliminary report of repeated non-compliance by the laboratory of a PHS funded faculty member. If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,

Michael P. Diamond, MD

Institutional Official

Senior Vice President for Research

Augusta University