



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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 6, 2020

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

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 October 30, 2020 letter providing additional requested information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University. According to the additional information provided, OLAW understands that a total of 16 rats were involved in the incident. The PI has confirmed that none of the data collected from the animals would be used for publication or as preliminary data in a grant application. The IACUC Chair provided a presentation and discussion of compliance related to animal welfare with everyone named on the protocol. The protocol was reviewed to ensure that everyone was aware of the details of procedures that are approved in the protocol. The University has reviewed project expenditure and is in the process of removing any non-compliant expenditures from the grant.

Thank you for your cooperation and for providing this additional information. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.  
Morse -S  
Date: 2020.11.06 13:43:17 -05'00'

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 15<sup>th</sup> Street, CA-3124  
Augusta, GA. 30912

October 30<sup>th</sup>, 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

RE: OLAW case A3307-X

Dear Dr. Diamond:

This letter is the follow-up report related to a preliminary report submitted to OLAW on October 14<sup>th</sup> regarding an incident in which a PHS funded PI was performing procedures on rats that had not been approved by the IACUC.

- The Laboratory Animal Facility Manager reported that Animal Services were having to contact a PI multiple times a day because it was necessary to replenish bottles of salt solution on four cages of group housed rats. When the Facility Manager checked the relevant Animal Use Protocol (AUP) on October 13<sup>th</sup>, 2020 it was determined that it did not include approval for offering medicated water to rats. When the PI was informed of this and asked to submit an amendment the PI realized that although he was approved to perform nephrectomy followed by DOCA pellet implant and offering of 0.9% salt solution to induce hypertension in mice, this procedure had not been approved for rats. The PI offered to stop the experiment immediately and to euthanize the animals while he waited for approval of a major amendment to his protocol.
- The Facility Manager asked the PI to contact the Attending Veterinarian before making any decision regarding disposition of the animals.
- The Attending Veterinarian and IACUC Chair conferred and agreed that because these were very valuable animals (1 year old genetically modified rats) they should be transferred to the AUP of another PI who is approved for the procedure and that the first PI should be added to that protocol in order to be able to maintain the rats while waiting for approval of his amendment.
- The Facility Manager reported the incident to the Attending Veterinarian and the IACUC through the electronic "Incident Report" system on October 14<sup>th</sup>, 2020.
- On October 14<sup>th</sup> the rats were transferred to an AUP that included the DOCA/salt hypertension model, the PI was added to that protocol and he submitted a major amendment for review by the IACUC.
- The number of rats per cage was reduced to ensure they had adequate salt solution available.
- A preliminary report was submitted to the IO and OLAW on October 14<sup>th</sup>.
- In response to the report, Dr. Morse, Director of Compliance Oversight at OLAW required that the following actions be taken:
  - That measures be taken to prevent recurrence of this incident
  - That the institution disclose non-compliance to any journal or funding application for which data from these animals was used.
  - The institution report this incident to the Chief Grants Management officer of the PHS

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funding component

- o Ensure that no charges related to the non-compliant activities are charged to the grant
- o Provide the date of the non-compliant activity and the number of animals involved.

The following actions have been taken:

- A total of 16 rats were subjected to uni-nephrectomy surgery between the dates of 9/23/2020 and 10/13/2020. Ten of these rats underwent a second surgery to place a subcutaneous DOCA pellet between the dates of 9/28/2020 and 10/12/2020. There was a five day interval between the two surgeries for each animal and they were offered salt solution following the second surgery. All of the animals will be euthanized by 11/3/2020.
- On October 18<sup>th</sup>, 2020 the PI was given a copy of the response from OLAW and confirmed that none of the data collected from the animals would be used for publication or as preliminary data in a grant application.
- The amendment to the PI's protocol was approved by the AU IACUC at their regularly scheduled meeting on October 22<sup>nd</sup>, 2020. The PI was advised not to perform any of these surgeries until this case report is closed by OLAW.
- The IACUC did not recommend any additional responses beyond those already identified by OLAW
- On October 30<sup>th</sup> the IACUC Chair provided a presentation and discussion of Compliance related to animal welfare in an appropriately socially distanced meeting with everyone named on the PI's protocol. Following the discussion the AUP was reviewed to ensure that everyone was aware of the details of procedures that are approved in the protocol.
- AU has reviewed project expenditure and is in the process of removing any non-compliant expenditures from the grant.

Submitted on behalf of the IACUC,

(b) (6)

Ruth Harris, PhD  
Regents Professor

Report received and approved by the Institutional Official,

(b) (6)

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

(b) (6)

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## **Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, November 2, 2020 7:34 AM  
**To:** Diamond, Michael  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Augusta University reportable incident - A3307-01 -Followup report

Thank you for this report, Dr. Diamond. We will respond soon.  
Axel Wolff

---

**From:** Diamond, Michael <michael.diamond@augusta.edu>  
**Sent:** Saturday, October 31, 2020 1:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Subject:** RE: Augusta University reportable incident - A3307-01 -Followup report

Dear Dr. Wolff,

Attached please find the follow-up report to the Augusta University reportable incident first reported to OLAW on 10/15/20.

Thank you.

Michael

Michael P. Diamond, MD  
Institutional Official  
Senior Vice President for Research  
Augusta University

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**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Friday, October 16, 2020 11:24 AM  
**To:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] RE: Augusta University reportable incident - A3307-01

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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:** Thursday, October 15, 2020 11:46 AM

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

**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>; (b) (6)

**Subject:** Augusta University reportable incident - A3307-01

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached is a letter to provide information on a reportable incident, along with our plan to correct the issue moving forward, both short and long term.

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

November 3, 2020

Ryan Lombardi  
Chief Grants Manager  
National Heart, Lung & Blood Institute  
Rockville, MD

RE: 5F31HL142183-03  
Notification of Non-Compliance with the PHS Policy on Humane Care  
and Use of Laboratory Animals at Augusta University  
OLAW Case A3307-X

Dear Mr. Lombardi,

I am writing to report an instance of non-compliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University (AU). AU self-reported to OLAW that the PI for the above referenced project performed procedures on rats that were not approved by the IACUC. Rats had undergone nephrectomies followed by DOCA pellet implantation and offering saline solution to induce hypertension, despite these procedures having been approved only in mice on the protocol.

AU has reviewed project expenditures and has removed any non-compliant expenditures from the grant.

Attached for your records is the correspondence between OLAW and AU regarding this matter.

Sincerely,

(b) (6)

Attachments: OLAW Letter Dated 10/18/2020  
Follow Up Report to OLAW Dated 10/30/2020

cc: [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)  
Michael P. Diamond, MD, Senior Vice President for Research  
Ruth Harris, Ph.D., IACUC Chair

Division of Sponsored Programs Administration

Mailing Address:  
1120 15<sup>th</sup> Street, CJ-3301  
Augusta, Georgia 30912

Office Address:  
1474 Laney Walker Blvd (PAV III)  
Augusta, Georgia 30909

T 706-721-2592  
F 706-721-4067 (Post Award)  
F 706-721-6478 (Pre Award)

[augusta.edu](http://augusta.edu)

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, November 4, 2020 7:13 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: 5F31HL142183-03 Notification of Non-Compliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University - OLAW Case A3307-X

Thank you. We will be in touch with the grants manager.

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

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**From:** (b) (6)  
**Sent:** Tuesday, November 3, 2020 4:37 PM  
**To:** Lombardi, Ryan (NIH/NHLBI) [E] <lombardr@nhlbi.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** 5F31HL142183-03 Notification of Non-Compliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University - OLAW Case A3307-X

Mr. Lombardi,

I am writing to report an instance of non-compliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University (see attached pdf).

AU has reviewed project expenditures and has removed any non-compliant expenditures from the grant.

Included in the attached pdf is the correspondence between OLAW and AU regarding this matter.

Sincerely,

(b) (6)



**AUGUSTA UNIVERSITY**

## Morse, Brent (NIH/OD) [E]

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**From:** Harris, Ruth <RUHARRIS@augusta.edu>  
**Sent:** Tuesday, October 20, 2020 3:56 PM  
**To:** Morse, Brent (NIH/OD) [E]  
**Subject:** Re: [EXTERNAL] OLAW Case A3307-X

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Brent  
Thank you for your response, this is very helpful  
Ruth

---

**From:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Sent:** Tuesday, October 20, 2020 3:41 PM  
**To:** Harris, Ruth <RUHARRIS@augusta.edu>  
**Subject:** RE: [EXTERNAL] OLAW Case A3307-X

Thank you for contacting OLAW for clarification. In similar incidents other institutions will often require retraining of a PI to ensure they are familiar with IACUC policies and procedures regarding the use of animals and expectations of submitting protocol amendments and awaiting IACUC approval before initiating animal activities. In addition, having the PI and his/her staff commit to reading the protocol or experiments before their conduct. Hope this helps.

Sincerely, Brent Morse

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

**From:** Harris, Ruth <RUHARRIS@augusta.edu>  
**Sent:** Tuesday, October 20, 2020 1:30 PM  
**To:** Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>  
**Subject:** Re: [EXTERNAL] OLAW Case A3307-X

Hello Keri

Thank you for sending Dr Morse's interim response to our incident report OLAW Case A3307-X. I have one question regarding what OLAW would consider acceptable "preventive measures". I am asking this to ensure that we take all necessary action as soon as possible. I left a phone message for Dr Morse yesterday but have not received a call back.

This incident involved a PHS funded investigator performing surgery on rats for which he was not approved. He self-reported his non-compliance and offered to kill the rats immediately, but due to their background we transferred the animals to another protocol. He has submitted an amendment to his protocol that will be discussed and voted on at this week's IACUC meeting. He will ensure all past and current expenses associated with these animals are charged to a non-NIH account, that he will not publish the data and will not use the data as preliminary data for any NIH-funded grant application.

We would appreciate any guidance you can provide regarding additional actions, such as specific training, that would be appropriate for this incident.

regards  
Ruth Harris



---

**From:** Walker, Keri (NIH/OD) [C] <[keri.walker@nih.gov](mailto:keri.walker@nih.gov)>  
**Sent:** Monday, October 19, 2020 8:30 AM  
**To:** Diamond, Michael <[michael.diamond@augusta.edu](mailto:michael.diamond@augusta.edu)>  
**Cc:** Harris, Ruth <[RUHARRIS@augusta.edu](mailto:RUHARRIS@augusta.edu)>; [REDACTED] (b) (6)  
**Subject:** [EXTERNAL] OLAW Case A3307-X

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Dear Dr. Diamond,

Attached please find Dr. Morse's interim response to OLAW Case A3307-X.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,  
Keri

*Keri Walker  
Program Analyst (Contractor)  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Dr., Suite 2500  
Bethesda, MD 20892  
301-435-2390  
[keri.walker@nih.gov](mailto:keri.walker@nih.gov)*



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Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

October 18, 2020

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

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 an October 15, 2020 letter, submitted on behalf of the IACUC and endorsed by you, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Augusta University. According to the information provided, OLAW understands that a PHS funded PI was performing procedures on rats that had not been approved by the IACUC. Rats had undergone nephrectomies followed by DOCA pellet implantation and offering saline solution to induce hypertension, although these procedures were only approved in mice on his protocol. Because these were very valuable animals (1 year old genetically modified rats) it was determined they should be transferred to the AUP of another PI who is approved for the procedure and that the first PI should be added to that protocol in order to be able to maintain the rats while waiting for approval of an amendment to his protocol.

OLAW understands that the only "corrective" measure was the transfer of the animals to another protocol and adding the PI to that protocol. There were no preventive measures described.

Although OLAW understands the desire to conserve the valuable animals, there is no provision in the PHS Policy for retroactive approval of a non-approved activity. Your institution would be expected to fully disclose the noncompliance to any journal to which data from this incident was submitted or used for any funding application. **Please be advised** that it is your institution's responsibility to report this incident to the Chief Grants Management Officer of the PHS funding component and to make sure that no expenses related to these noncompliant activities are charged to the grant. Please copy OLAW on your communication and reference OLAW case A3307-X. Please also include measures to prevent a recurrence of this incident, the date(s) of the noncompliant procedures and the approximate number of animals involved. **This case will remain open.**

The prompt consideration of this matter by Augusta University was consistent with the philosophy of institutional self-regulation as far as it went. We appreciate being informed of this matter and OLAW will send a final response once the required information is provided. Please feel free to contact me if I can provide further guidance.

Sincerely,

**Brent C. Morse -S**

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

Digitally signed by Brent C. Morse -  
S  
Date: 2020.10.19 07:12:52 -04'00'

cc: IACUC Contact

A3307-X



**AUGUSTA**  
UNIVERSITY

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

October 15<sup>th</sup>, 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 describes a report received on Wednesday, October 14<sup>th</sup>, 2020 that a PHS funded PI was performing procedures on rats that had not been approved by the IACUC. The Laboratory Animal Facility Manager reported the following:

- Laboratory Animal Services were having to contact a PI multiple times a day because it was necessary to replenish bottles of salt solution on four cages of group housed rats. When the Facility Manager checked the relevant Animal Use Protocol (AUP) on October 13<sup>th</sup>, 2020 it was determined that it did not include approval for offering medicated water to rats. When the PI was informed of this and asked to submit an amendment the PI realized that although he was approved to perform nephrectomy followed by DOCA pellet implant and offering of 0.9% salt solution to induce hypertension in mice, this procedure had not been approved for rats. The PI offered to stop the experiment immediately and to euthanize the animals while he waited for approval of a major amendment to his protocol.
- The Facility Manager asked the PI to contact the Attending Veterinarian before making any decision regarding disposition of the animals.
- The Attending Veterinarian and IACUC Chair conferred and agreed that because these were very valuable animals (1 year old genetically modified rats) they should be transferred to the AUP of another PI who is approved for the procedure and that the first PI should be added to that protocol in order to be able to maintain the rats while waiting for approval of his amendment.
- The Facility Manager reported the incident to the Attending Veterinarian and the IACUC through the electronic "Incident Report" system on October 14<sup>th</sup>, 2020.
- On October 14<sup>th</sup> the rats were transferred to an AUP that included the DOCA/salt hypertension model, the PI was added to that protocol and he submitted a major amendment for review by the IACUC. The amendment will be voted on by the IACUC committee at their next regularly scheduled meeting on October 22<sup>nd</sup>, 2020.
- This incident will be discussed at the IACUC meeting to determine whether any further corrective action is needed.
- The number of rats per cage has been reduced to ensure they have adequate salt solution available.

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)

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

10/15/20

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**Wolff, Axel (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, October 16, 2020 7:25 AM  
**To:** SVPRESEARCH  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Augusta University reportable incident - 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:** Thursday, October 15, 2020 11:46 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; Harris, Ruth <RUHARRIS@augusta.edu>; (b) (6)  
(b) (6)  
**Subject:** Augusta University reportable incident - A3307-01

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached is a letter to provide information on a reportable incident, along with our plan to correct the issue moving forward, both short and long term.

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