



**AUGUSTA**  
UNIVERSITY

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

May 20<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 is to provide a second update on the reported unexpected adverse event that occurred during the night of Sunday April 19<sup>th</sup>, 2020. On Monday April 20<sup>th</sup>, 2020 an Augusta University Veterinarian submitted an incident report regarding the loss of animals in the Summerville rodent facility. Failure of a pneumatic compressor resulted in excessively high temperatures in the animal rooms and 18 rats and 29 mice died from hyperthermia.

This incident was initially reported to OLAW on April 21<sup>st</sup> and a follow-up letter describing the corrective actions that had been taken was sent on April 29<sup>th</sup>. In that letter I failed to specifically state that the HVAC compressor had been repaired. This letter is to confirm that the compressor was repaired during the week following the incident and is maintaining appropriate room temperatures in the facility.

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

Submitted on behalf of the IACUC,

(b) (6)

Report received and approved by the Institutional Official,

(b) (6)

*MP*

*5/20/20*

Date

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

Phone 706-721-4479 Fax 706-721-7299 <https://www.augusta.edu/mcg/phy/>  
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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 22, 2020 8:03 AM  
**To:** Diamond, Michael  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: A3307-01 Augusta University Adverse Event second update

Thank you for this update, Dr. Diamond. I will add it to the case file.  
Axel Wolff

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**From:** Diamond, Michael <michael.diamond@augusta.edu>  
**Sent:** Wednesday, May 20, 2020 3:10 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** SVPRESEARCH <SVPRESEARCH@augusta.edu>; (b) (6)  
**Subject:** A3307-01 Augusta University Adverse Event second update

Dear Dr. Wolff,

This email and the associated attachment provides a second update to an adverse event on April 19, 2020. Specifically, we are confirming that the HVAC compressor has been repaired.

Thank you.

Sincerely,

Michael

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



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 4, 2020

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

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

Dear Dr. Diamond,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 29, 2020 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Augusta University, following up on an initial report on April 21, 2020. According to the information provided, OLAW understands that 18 rats and 21 mice died from hyperthermia after the room overheated due to a failed pneumatic compressor unit in the heating, ventilation, air conditioning (HVAC) system. The pager alarm notification also failed due to a software problem.

The corrective actions consisted of moving the surviving animals to a different campus of the university, correcting the software problem, and adding an additional person to the pager system. The alarm system will be tested regularly and the veterinarian will be added to the telephone alert system. Investigators were given the option of keeping animals at the other site.

Based on its assessment of this investigation, OLAW understands that measures have been implemented to correct and to reduce the likelihood of a recurrence of this problem. We assume that the HVAC compressor was repaired. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



**AUGUSTA**  
UNIVERSITY

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

April 29<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 is to provide an update on the reported unexpected adverse event that occurred during the night of Sunday April 19<sup>th</sup>, 2020. On Monday April 20<sup>th</sup>, 2020 an Augusta University Veterinarian submitted an incident report regarding the loss of animals in the Summerville rodent facility. Failure of a pneumatic compressor resulted in excessively high temperatures in the animal rooms and 18 rats and 29 mice died from hyperthermia.

When the equipment failed an alarm should have been triggered and relayed to a Facilities manager through a pager system. The Facilities manager in turn should have contacted Laboratory Animal Services. At the time of the initial report to OLAW we did not know why this alarm process failed. We have now determined that a software update inactivated the pager alarm. This has now been corrected and a second pager number has also been added to the alarm process so that two members of the Facilities team will be alerted if the heating system on the Summerville campus fails. The alarm system will be tested on a regular basis and we hope to add a phone alert to a member of the veterinary staff in the near future. Meanwhile all of the animals that had been housed at Summerville are housed on the Heath Sciences campus of Augusta University and the investigators have been given the option of keeping their animals there permanently. The distance between the two campuses is approximately 2.5 miles.

The incident was reported to the IACUC at a regularly convened committee meeting on Thursday April 23<sup>rd</sup> and the incident will be an agenda item for the May meeting in order to provide follow-up information. For reporting purposes, our Assurance Number (A3307-01) is provided.

Submitted on behalf of the IACUC,

(b) (6)



Report received and approved by the Institutional Official,  
(b) (6)



4/29/20  
Date

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

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 1, 2020 7:11 AM  
**To:** SVPRESEARCH  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Augusta University update to our initial report - A3307-01

Thank you for this report, (b) (6) We will send a response soon.  
Axel Wolff

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**From:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Sent:** Wednesday, April 29, 2020 8:20 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; (b) (6)  
(b) (6)  
**Subject:** Augusta University update to our initial report - A3307-01

This letter is provided as AU's update to our initial report from 4/21/20, and your response from 4/22/20. If you have any questions please contact us. Thanks.

(b) (6)

A3307-W



AUGUSTA  
UNIVERSITY

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

April 21<sup>st</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 is a report of an unexpected adverse event reported on Monday April 20<sup>th</sup>, 2020. An Augusta University Veterinarian submitted an incident report regarding the loss of animals in the Summerville rodent facility:

On the morning of April 20<sup>th</sup> 18 rats and 29 mice were found dead in conventional rodent housing in the Science building on Summerville campus. At 9.00 a.m. room temperature was approximately 80°F and thermometers located in the rooms indicated that temperatures had reached a maximum of 111°F during the previous 24 hours. All of the animals were healthy, had no sign of disease and it is assumed that they died from hyperthermia. A research staff member had been in the facility on the afternoon of April 19<sup>th</sup> when room temperature was normal and it is assumed that the high temperatures developed during the night.

The Science building supervisor reported that during the night of April 19<sup>th</sup> there was a failure of a pneumatic compressor. When this equipment fails, the HVAC switches to the "heat" setting and produces abnormally high temperatures. In this situation an alarm should be triggered which is relayed to a facilities manager through a pager system. Facilities then contacts LAS to report the problem. This alarm process failed and LAS and Facilities continue to investigate to determine whether it was a failure of the alarm, a failure of the pager or a failure of personnel to respond to the page.

Eleven of the rats belonged to a PHS funded investigator, one rat and four of the mice were sentinels belonging to LAS and the remainder of the animals belonged to two investigators whose research is supported by intramural funding. All remaining animals have been moved to the Health Sciences campus and will remain there until a disposition is determined. No animals will be housed in the Summerville Vivarium until the cause of the heating failure and the failure to raise a response to such a failure have been identified and a procedure established to prevent a recurrence of this event.

The IACUC is meeting on Thursday April 23<sup>rd</sup> and this incident will be an agenda item to ensure appropriate follow-up. For reporting purposes, our Assurance Number (A3307-01) is provided.

Submitted on behalf of the IACUC,

(b) (6)



Phone 706-721-4479 Fax 706-721-7299 <https://www.augusta.edu/mcp/phy/>  
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Report received and approved by the Institutional Official. (b) (6)

4/21/20

Date

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

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 22, 2020 7:25 AM  
**To:** SVPRESEARCH  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Augusta University unexpected adverse event 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, April 21, 2020 5:06 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; (b) (6) SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Subject:** Augusta University unexpected adverse event report - A3307-01

Attached please find our letter to OLAW describing the incident that we wish to report. We are continuing to investigate the cause, and will develop a response plan once the cause is understood.

Thank you.

Michael

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

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 22, 2020 7:28 AM  
**To:** SVPRESEARCH  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Augusta University unexpected adverse event report - A3307-01

I see you are still investigating, so I will accept this as a preliminary report and await the final after corrective actions have been instituted.  
Axel Wolff

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**From:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Sent:** Tuesday, April 21, 2020 8:26 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Augusta University unexpected adverse event report - A3307-01

Attached please find our letter to OLAW describing the incident that we wish to report. We are continuing to investigate the cause, and will develop a response plan once the cause is understood.

Thank you.

Michael

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

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**From:** SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Sent:** Tuesday, April 21, 2020 9:05 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Diamond, Michael <michael.diamond@augusta.edu>; (b) (6) SVPRESEARCH <SVPRESEARCH@augusta.edu>  
**Subject:** Augusta University unexpected adverse event report - A3307-01

Attached please find our letter to OLAW describing the incident that we wish to report. We are continuing to investigate the cause, and will develop a response plan once the cause is understood.

Thank you.

Michael

Michael P. Diamond, MD  
Institutional Official

Senior Vice President for Research  
Augusta University