

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

March 9, 2021

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

Re: Animal Welfare Assurance A3307-01 [OLAW Case 1A]

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 the March 3, 2021 letter in response to the March 2, 2021 letter sent from the Office of Laboratory Animal Welfare (OLAW).

The previous report dated February 19, 2021 stated a scheduled semiannual laboratory inspection identified deficiencies, which included unapproved overnight housing of mice in the laboratory. The principal investigator (PI) confirmed the noncompliance had occurred and the report stated it was the third incident for the PI in 12 months. Previous reports involved cages of mice discovered dehydrated with no food or water and euthanasia of animals by approved method but not in accordance with institutional policy for use of the home cage for euthanasia. The lab members were retrained on weaning and euthanasia procedures as corrective actions.

The PI was directed by the IACUC Chair to halt research involving animals until personnel on the protocol received training in animal welfare and participated in review of the approved protocol. The training was completed the following day. The incident involving unapproved housing was discussed at the February 25th convened IACUC meeting to determine if additional recommendations were necessary.

The final report states the committee voted that if another incident is reported for this PI in the next 12 months, then all members of the laboratory will be required to attend an off-site IACUC 101 course. The PI has been informed of the IACUC's decision.

It is noted that this investigator receives PHS funding. Based on its assessment of this explanation, OLAW understands that the Augusta 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 Jacquelyn T. Tubbs, Digitally signed by Jacquelyn T. Tubbs -S Date: 2021.03.09 12:35:01 -05'00' Jacquelyn T. Tubbs, DVM, DACLAM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact



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

March 3rd, 2021

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 the final report of non-compliance by the laboratory of a PHS funded member of faculty. (OLAW case A3307-1A)

- On the morning of February 17th two members of the IACUC Committee performed a scheduled semi-annual laboratory inspection for a PHS funded investigator at Augusta University. They identified a number of deficiencies including housing of mice in the laboratory overnight when the PI does not have approval of overnight or satellite housing. The laboratory member who met with the committee members reported that mice had previously been kept in the lab for up to 3 days. In a subsequent phone conversation with the IACUC Chair the PI acknowledged that mice had been in the laboratory overnight, but disputed whether animals had been kept there for any longer periods of time.
- This was the third incident report for this PI in twelve months (February 2020, January 2021, February 2021). The first report was that LAS staff found three cages of dehydrated weaned mice without food or water. The second was that a member of the PIs staff was euthanizing mice using a method approved in the PIs protocol, but was not following our policy of keeping animals in their home cage for euthanasia. The members of the laboratory were retrained in weaning and euthanasia procedures following the first two incidents.
- The IACUC Chair contacted the PI on the afternoon of February 17th requiring that research involving animals stop until everyone named on the PI's protocol received training in animal welfare and participated in review of their approved protocol. This training was completed on the afternoon of February 18th.
- This issue was discussed at a convened meeting of the IACUC committee on February 25th.
 The committee voted to require that if there is another reported incident for this PI in the next 12 months, then all members of the laboratory will be required to attend an off-site IACUC 101 course. The cost of this training will have to be covered by non-grant funds.
- The PI was informed of the IACUC Committee decision by email on February 25th and acknowledged the requirement.

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)

3/3/21

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]

From: Sent:	OLAW Division of Compliance Oversight (NIH/OD) Friday, March 5, 2021 7:18 AM
To:	SVPRESEARCH
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Augusta University Incident Final Report Letter- A3307-1A

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

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

From: SVPRESEARCH <svpresearch@augusta.edu></svpresearch@augusta.edu>				
Sent: Thursday, March 4, 2021 12:53 PM				
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>				
Cc:	^{(b) (6)} Diamond, Michael			
<michael.diamond@augusta.edu>;</michael.diamond@augusta.edu>	(b) (6)			
(b) (6)				

Subject: Augusta University Incident Final Report Letter- A3307-1A

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached please find the incident report final update of non-compliance by the laboratory of a PHS-funded member of faculty (OLAW case A3307-1A). If you have any questions, feel free to contact us by phone or by e-mail.

1

Best Regards,

Michael P. Diamond, MD

Institutional Official

Senior Vice President for Research

Augusta University



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

March 2, 2021

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

FOR EXPRESS MAIL:

Re: Animal Welfare Assurance A3307-01 [OLAW Case 1A]

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 February 19, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Augusta University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Augusta University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: unapproved housing of animals in the laboratory. The final report states on February 17, 2021 a scheduled semiannual laboratory inspection was conducted. Deficiencies were identified and included the housing of mice in the laboratory overnight, which the principal investigator (PI) was not approved for per protocol. The PI confirmed mice had been housed in the laboratory overnight. It is stated this is the third incident for the PI in 12 months. Previous reports involved cages of mice discovered dehydrated with no food or water and euthanasia of animals by approved method but not in accordance with institutional policy for use of the home cage for euthanasia. In response, the lab members were retrained on weaning and euthanasia procedures.

The IACUC Chair instructed the PI to halt research involving animals until personnel on the protocol received training in animal welfare and participated in review of the approved protocol. The report states training was completed the next day. The incident involving unapproved housing was discussed at the February 25th convened IACUC meeting to determine if additional recommendations were necessary.

Please provide an update to OLAW on the committee's final decision related to the most recent incident and plans to prevent future recurrence. Please provide an update to this Office by **March 31, 2021**.

We appreciate being informed of these matters.

Sincerely, Jacquelyn T. Tubbs -S Jace 2021.03.02 15.04:47-05'00' Jacquelyn T. Tubbs, DVM, DACLAM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

A3307-1A



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

February 19th, 2021

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 the report of non-compliance by the laboratory of a PHS funded member of faculty.

- On the morning of February 17th two members of the IACUC Committee performed a scheduled semi-annual laboratory inspection for a PHS funded investigator at Augusta University. They identified a number of deficiencies including housing of mice in the laboratory overnight when the PI does not have approval of overnight or satellite housing. The laboratory member who met with the committee members reported that mice had previously been kept in the lab for up to 3 days. In a subsequent phone conversation with the IACUC Chair the PI acknowledged that mice had been in the laboratory overnight, but disputed whether animals had been kept there for any longer periods of time.
- This was the third incident report for this PI in twelve months (February 2020, January 2021, February 2021). The first report was that LAS staff found three cages of dehydrated weaned mice without food or water. The second was that a member of the PIs staff was euthanizing mice using a method approved in the PIs protocol, but was not following our policy of keeping animals in their home cage for euthanasia. The members of the laboratory were retrained in weaning and euthanasia procedures following the first two incidents.
- The IACUC Chair contacted the PI on the afternoon of February 17th requiring that research involving animals stop until everyone named on the PI's protocol received training in animal welfare and participated in review of their approved protocol. This training was completed on the afternoon of February 18th.
- The most recent incident of housing animals in the laboratory and the issue of recurring noncompliance will be discussed at the next convened meeting of the IACUC committee on February 25th to determine whether there are additional recommendations for response.
- The PI will be informed of the IACUC Committee decision by email on February 25th.

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,

2/19/21

(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

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, February 22, 2021 7:35 AM
To:	SVPRESEARCH
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Augusta University new 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></svpresearch@augusta.edu>	
Sent: Friday, February 19, 2021 3:47 PM	
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>	(b) (6)
Cc: Diamond. Michael <michael.diamond@augusta.edu>;</michael.diamond@augusta.edu>	(0) (0)
	(b) (6)

Subject: Augusta University new incident report - A3307-01

On behalf of Dr. Michael P. Diamond, AU Institutional Official, attached please find a new incident report of non-compliance by the laboratory of a PHS-funded member of AU faculty. 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