



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

December 9, 2022

Re: Animal Welfare Assurance
#A3180-01 [OLAW Case 6N]

Dr. Robert Nobles
Vice President for Research Administration
Emory University
1599 Clifton Road NE - 4th floor
Atlanta, GA 30322

Dear Dr. Nobles,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 29, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Emory University following up on an initial September 2, 2022 notification by telephone.

According to the information provided, this office understands that the Emory University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to the conduct of animal activities without prior IACUC review and approval. The final report states on April 19, 2022, a laboratory's surgeon was performing a surgery assessment and discovered that the lab was performing a surgical procedure that was not described in the protocol. Per the report, there were no animal deaths. In response to the incident, the following corrective actions were implemented:

- The DAR vet recommended the surgeon retake the Aseptic Surgery Lecture, work with the DAR training staff to do hands on surgical training/aseptic technique training and schedule another surgery assessment.
- The lab was requested to submit a modification for the unapproved surgery or to follow the protocol as written.

It is understood the surgeon passed the Aseptic Surgery Lecture on May 12, 2022 and passed the surgical assessment on September 22, 2022. The lab also modified their surgical procedure, and all amendments were approved by the Emory IACUC on May 25, 2022. Per the report, the IACUC considers these corrective actions to be appropriate.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Emory 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.

*Page 2 – Dr. Nobles
December 9, 2022
OLAW Case A3180-6N*

Sincerely,

Jacquelyn T.

Tubbs -S

Jacquelyn Tubbs, DVM, DACLAM

Senior Animal Welfare Program Specialist

Division of Compliance Oversight

Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.12.09 14:29:54
-0500

cc: IACUC Contact



EMORY
UNIVERSITY

Institutional Animal Care and Use Committee

November 29, 2022

Jacquelyn Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Re: Emory University, Animal Welfare Assurance #A3180-01

Dear Dr. Tubbs,

The Emory University Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, is reporting the results of an event as required by section IV, F, 3a of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). A preliminary report was provided via phone call to your office on 8/12/22. This is the final report regarding a protocol violation of performing an unapproved surgical procedure. The associated NIH-funded grant is NIH 1 R01 EB029857-01.

Situation and Assessment

On April 19, 2022, the lab's surgeon was performing a surgery assessment where it was discovered that the lab was performing a surgical procedure, which was not in the approved protocol. No animal deaths were involved.

The corrective actions to prevent a recurrence were:

- DAR vet staff recommended that the surgeon retake the Aseptic Surgery Lecture, work with the DAR training staff one on one to do hand on surgical training/aseptic technique training and then schedule another surgery assessment. The lab's surgeon completed and passed the Aseptic Surgery Lecture on May 12, 2022, and completed and passed his surgical assessment on September 22, 2022 following hands-on training.
- The lab was asked to provide a modification for the unapproved surgery or to follow the protocol as written. The lab modified their surgical procedure, and all amendments were approved by the Emory IACUC on May 25, 2022.

The IACUC believes its investigation of this incident was thorough and the corrective actions appropriate to prevent a similar occurrence. If you have questions regarding this incident, please contact me or (b) (6)

(b) (6)

Thank you,

DocuSigned by: 11/30/2022 | 4:24 PM EST
14785F4848B...

Robert Nobles, DrPH, MPH, CIP
Vice President for Research Administration
Emory University
1599 Clifton Road NE
Atlanta, GA 30322

(b) (6)

Email: Robert.e.nobles@emory.edu

McCoy, Devora (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Thursday, December 1, 2022 10:50 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Emory University, Animal Welfare Assurance #A3180-01

Follow Up Flag: Follow up
Flag Status: Completed

Good morning,

Thank you for the final report. I will send an official response soon.

J. Tubbs

From: (b) (6)
Sent: Thursday, December 1, 2022 9:59 AM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Emory University, Animal Welfare Assurance #A3180-01

Good morning Dr. Tubbs,

Please see the attached final letter to OLAW regarding an event that was preliminarily reported to your office. The second event that was preliminarily reported is still under investigation. Please let us know if you have any questions or concerns.

Happy Holidays!

(b) (6)



Initial Report of Noncompliance

By: J. Tubbs

Date: 09-02-2022

Time: 852A

Name of Person reporting: (b) (6)

Telephone #:

Fax #:

Email: (b) (6)

Name of Institution: Emory University

Assurance number: A3180-01

Did incident involve PHS funded activity? TBD

Funding component:

Was funding component contacted (if necessary): _____

What happened?

Unapproved procedure performed, but no animal deaths (mice) occurred in April 2022. 2nd case involved Protocol violation because individuals were not using the correct analgesia and used an expired substance in an animal for a terminal procedure (mice) in August 2022.

Species involved: Mice

Personnel involved:

Dates and times: April 2022

Animal deaths: none

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:
60-90d

OFFICE USE ONLY

Case # _____