

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

EOR 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

February 15, 2023

Re: Animal Welfare Assurance #A3180-01 [OLAW Case 60]

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

Dear Dr. Nobles,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 7, 2023 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 failure to adhere to the IACUC-approved protocol. The final report states on July 28, 2022, it was determined a laboratory performed animal surgeries on mice but did not administer the approved local analgesia prior to surgery. In response to the finding, the following corrective actions were implemented:

- The lab ordered the local analgesia and will use it in future surgeries.
- The Principal Investigator confirmed to the IACUC office that the research team understands the procedure, including requirement for analgesia, as approved in the protocol and will follow it correctly.

It is noted that this research is supported by PHS funding and the IACUC found the corrective actions to be appropriate. 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.

Sincerely, Jacquelyn T. Tubbs -S Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

3180-60



Institutional Animal Care and Use Committee

February 7, 2023

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 8/24/22. This is the final report regarding a protocol violation of not providing an approved analgesia. The associated NIH-funded grants are NIH RF1 AG061175 and R01 AG079199.

Situation and Assessment

On July 28, 2022, it was discovered that a protocol violation occurred in which the laboratory conducted animal surgeries on mice but did not provide the approved local analgesia prior to surgery. No deaths were involved.

The corrective actions to prevent a recurrence were:

- The lab immediately ordered the local analgesia and will use it in future surgeries.
- The PI confirmed to the IACUC office that the research team understands the procedure, including requirement for analgesia, as approved in the protocol and will follow it correctly.

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) (6)

(b) (6)

Thank you,

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:                           | Wednesday, February 8, 2023 11:36 AM                     |
| To:                             | (b) (6)  |
| Cc:                             | OLAW Division of Compliance Oversight (NIH/OD)           |
| Subject:                        | RE: Emory University, Animal Welfare Assurance #A3180-01 |
| Follow Up Flag:<br>Flag Status: | Follow up<br>Flagged                                     |
| riag Status.                    | паудец   |

Hello,

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

## Happy Wednesday.

J. Tubbs

| From: (b) (6)   |         |
|---|---------|
| Sent: Wednesday, February 8, 2023 11:28 AM                                      |         |
| To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov></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 letters to OLAW. If there are any questions, please feel free to contact me.

Kind regards,

(b) (6)

13180-60



## **Initial Report of Noncompliance**

By: J. Tubbs

Date:

09-02-2022

Time: 855A

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?

Case involved a protocol violation regarding individuals that were not using the correct analgesia and used an expired substance in an animal for a terminal procedure.

Species involved: Mice Personnel involved: Dates and times: August 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 #