



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

March 30, 2022

Re: Animal Welfare Assurance
#A3180-01 (OLAW Case 6H)

Dr. Robert Nobles
Vice President for Research Administration
Emory University
1599 Clifton Road NE – 1599-001-1BE
Atlanta, GA 30322

Dear Dr. Nobles,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 14, 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 February 1, 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 December 14, 2021, it was determined that analgesia was not being administered as per protocol. In response to the incident, the following corrective actions were implemented:

- A Memo of Action letter was sent to the principal investigator giving the options that either all surgeries should cease until the correct analgesia has been provided to the lab or that the lab correctly follow their approved protocol regarding the use of analgesia.
- A modification to the protocol regarding the use of analgesia was submitted by the lab and approved on February 11, 2021 by the IACUC.

The IACUC determined the corrective actions were appropriate to prevent recurrence of this type of incident, and it is noted that this research is supported by NIH 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.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.03.30 14:21:00 -0400

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



EMORY
UNIVERSITY

Institutional Animal Care and Use Committee

March 14 , 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 2/1/22. This is the final report regarding a protocol violation of the use of analgesia. The associated NIH-funded grants are R41CA261544-01 and 1R21CA259935-01.

Situation and Assessment

On December 14, 2021, it was determined that analgesia was not being used as per protocol.

The corrective actions to prevent a recurrence were:

- A Memo of Action letter was sent to the principal investigator giving the options that either all surgeries should cease until the correct analgesia has been provided to the lab or that the lab correctly follow their approved protocol regarding the use of analgesia .
- A modification to the protocol regarding the use of analgesia was submitted by the lab and approved by the IACUC Committee on 2/11/22.

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)

Thank you, (b) (6)

3/22/2022 | 4:34 PM EDT

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

Email: Robert.e.nobles@emory.edu

Tubbs, Jai (NIH/OD) [E]

From: (b) (6)
Sent: Wednesday, March 23, 2022 2:03 PM
To: Tubbs, Jai (NIH/OD) [E]
Cc: (b) (6)
Subject: [EXTERNAL] Final OLAW letters for Emory University, Animal Welfare Assurance #A3180-01
Attachments: Please_DocuSign_Final_letter_to_OLAW-3-2022_.zip;
Please_DocuSign_Final_letter_to_OLAW-4-2022_.zip;
Please_DocuSign_Final_letter_to_OLAW-1-2022_.zip
Follow Up Flag: Follow up
Flag Status: Flagged

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Good afternoon Dr. Tubbs,

Please find the attached final OLAW letters. If there are any concerns, please feel free to contact me. This is my first time sending them via DocuSign. Please let me know if you need them in a different format. There should be four in all.

Warm Regards,

(b) (6)



A3180-6H

Initial Report of Noncompliance

By: J. Tubbs

Date: **02-01-2022**

Time: 307P

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

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?

Protocol violation- wrong dose of analgesia administered.

Species involved: mice

Personnel involved:

Dates and times: ~Dec 2021

Animal deaths: none

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

Corrective action plan in development

Projected submission to OLAW of final report from Institutional Official:

60-90d

OFFICE USE ONLY

Case # _____