



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

July 7, 2022

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

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 June 16, 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 May 14, 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 use of an analgesic in animals that was not included in the approved protocol. The final report states on March 2, 2022, it was determined an unapproved analgesic was administered to animals (mice per the preliminary report). It is understood that no animal deaths occurred, and the following corrective actions were implemented to prevent future recurrence:

- The lab submitted an amendment to add the analgesic to the protocol. The amendment was approved on April 7, 2022.
- Post-approval monitoring by the IACUC office occurred on March 15, 2022.

It is noted the research is supported by PHS funding and the IACUC determined the corrective actions were 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

Digitally signed by Jacquelyn T.
Tubbs-S
Date: 2022.07.07 13:16:34 -0400

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

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: Nobles, Robert E. <robert.e.nobles@emory.edu>
Sent: Thursday, July 7, 2022 5:42 PM
To: McCoy, Devora (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD); I ACUC
Subject: Re: [External] OLAW Cases A3180-6K, A3180-6L, and A3180-6M

Thank you for your review and response. We appreciate the collaboration and oversight.

Be well and have a great evening.

Robert

Robert Nobles, DrPH, MPH
Vice President for Research Administration

Emory University
1599 Clifton Road NE
Atlanta, GA 30322

(b) (6)

Email: robert.e.nobles@emory.edu
URL: www.or.emory.edu

(b) (6)

From: "McCoy, Devora (NIH/OD) [E]" <devora.mccoy@nih.gov>
Date: Thursday, July 7, 2022 at 2:37 PM
To: "Nobles, Robert E." <robert.e.nobles@emory.edu>
Cc: "OLAW Division of Compliance Oversight (NIH/OD)" <olawdco@od.nih.gov>, I ACUC <iacuc2@emory.edu>
Subject: [External] OLAW Cases A3180-6K, A3180-6L, and A3180-6M

Good afternoon Dr. Nobles,

Attached please find Dr. Tubbs' final responses to OLAW Cases A3180-6K, A3180-6L, and A3180-6M. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst

Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Tubbs, Jai (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Tuesday, July 5, 2022 8:28 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Emory University, Animal Welfare Assurance #A3180-01

Hello,,

Thank you for the reports, we will send an official response soon.

Kind Regards,

J. Tubbs

From: (b) (6)
Sent: Tuesday, July 5, 2022 7:52 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 reports from Emory University.

Kind regards,

(b) (6)

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3180-6L



EMORY
UNIVERSITY

Institutional Animal Care and Use Committee

June 16, 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 5/14/22. This is the final report regarding a protocol violation of using unapproved analgesia. The associated NIH-funded grant is NIH DK104125.

Situation and Assessment

On March 2, 2022, it was determined that unapproved analgesia was used. No animal deaths were involved.

The corrective actions to prevent a recurrence were:

- The lab submitted an amendment to add the unapproved analgesia to the protocol. The amendment was approved via DMR on April 7th, 2022.
- A PAM was performed by the IACUC office on 3-15-2022.

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)

Thank you, (b) (6) 6/23/2022 | 5:30 PM EDT

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

Tubbs, Jai (NIH/OD) [E]

From: (b) (6)
Sent: Tuesday, July 5, 2022 7:52 AM
To: Tubbs, Jai (NIH/OD) [E]
Cc: (b) (6)
Subject: [EXTERNAL] Emory University, Animal Welfare Assurance #A3180-01
Attachments: DocuSign_Final_letter_to_OLAW-6-2022_E.pdf; DocuSign_Final_letter_to_OLAW-6-2022_K.pdf; DocuSign_Final_letter_to_OLAW-6-2022_W.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Good morning Dr. Tubbs,

Please see the attached final reports from Emory University.

Kind regards,

(b) (6)

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Initial Report of Noncompliance

By: J. Tubbs

Date: 05-13-2022 Time: 1006A

Name of Person reporting: (b) (6)
Telephone #:
Fax #:
Email:

Name of Institution: Emory University
Assurance number: A3180-01

Did incident involve PHS funded activity? yes
Funding component:
Was funding component contacted (if necessary):

What happened?
Protocol violation- provided analgesia not in protocol.

Species involved: mice
Personnel involved:
Dates and times:
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 #