

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 6M]

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 failure to adhere to the IACUC-approved protocol and poor recordkeeping. The final report states an unapproved analgesic was administered to animals (mice per the preliminary report). It was also determined the lab had incomplete post-operative monitoring documentation for the animals. No animal deaths are associated with the noncompliance, and the following corrective actions were implemented in response to the violations:

 Post-approval monitoring by the IACUC office was performed and the lab was coached on utilizing the analgesia approved in the protocol and on adhering to the protocol.

It is noted that this 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 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></robert.e.nobles@emory.edu>
Sent:	Thursday, July 7, 2022 5:42 PM
То:	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.

(b) (6)

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

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 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: Sent: Tuesday, July 5, 2022 7:52 AM To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov> Cc: Subject: [EXTERNAL] Emory University, Animal Welfare Assurance #A3180-01

Good morning Dr. Tubbs,

Please see the attached final reports from Emory University.

Kind regards,

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Institutional Animal Care and Use Committee

3180-6M

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 and having incomplete post-op monitoring documentation. The associated NIH-funded grant is NIH 1 R01 EB029857-01.

Situation and Assessment

On February 2, 2022, it was determined that unapproved analgesia was used, and that the lab had incomplete post-op monitoring documentation. No animal deaths were involved.

The corrective action to prevent a recurrence was:

 A PAM was performed by the IACUC office on 2-15-2022 where the lab was coached on using the analgesia that was approved in the protocol and coached on correctly following the approved protocol.

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 | 5:31 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]

(b) (6)
Tuesday, July 5, 2022 7:52 AM
Tubbs, Jai (NIH/OD) [E]
(b) (6)
[EXTERNAL] Emory University, Animal Welfare Assurance #A3180-01
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 Flagged

Good morning Dr. Tubbs,

Please see the attached final reports from Emory University.

Kind regards,



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A 3180-6M



Initial Report of Noncompliance

By: J. Tubbs

Date:

05-13-2022

Time: 1006A

Name of Person reporting: 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- not monitoring animals as per 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 #_____