



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 6K]

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 conduct of animal activities without prior IACUC review and approval, including the conduct of animal activities beyond the protocol expiration date. It is stated on March 2, 2022, an unapproved terminal procedure was performed on a mouse on a lapsed protocol. The following corrective actions were implemented in response to the incident and deemed appropriate by the IACUC:

- The lab was instructed to cease all animal activities until the protocol's triennial submission was approved, which occurred on April 28, 2022.
- The principal investigator met with the Associate Vice President of Research Compliance and Regulatory Affairs to discuss the noncompliance on April 27, 2022.

It is noted that this protocol 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.

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.07.07 13:14:38 -04'00'

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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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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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 performing an unapproved procedure and performing a surgery on a lapsed protocol. The associated NIH-funded grants are R01 HL138410-01A1 and R01 DK110409-01A1.

Situation and Assessment

On March 2, 2022, it was determined that a single, unapproved terminal procedure was performed on a single mouse on a lapsed protocol.

The corrective actions to prevent a recurrence were:

- The lab was told to cease all animal activities until the protocol's triennial submission was approved. The triennial renewal was approved on April 28th, 2022.
- The PI met with the Associate Vice President of Research Compliance and Regulatory Affairs to discuss the violation. The meeting occurred on April 27th, 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, (b) (6) 6/23/2022 | 5:32 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



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- performing unapproved procedure and performed one procedure on a lapsed 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 # _____