



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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 1, 2022

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

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 9, 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 April 22, 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 failure to adhere to institutional policies, the conduct of an unapproved experimental study, and the use of an unapproved substance. The final report states on March 7, 2022, a lab performed an experimental study that was not approved in the protocol and used an unapproved virus vector in the study. On March 9th, it was determined the lab had overcrowded mouse cages, which resulted in the deaths of 3 mice, and had a weaning policy violation. The following corrective actions were implemented in response to the noncompliance:

- The vet staff assumed monitoring responsibilities of experimental animals.
- The lab was told to stop research with the unapproved agent, to meet with the Vice President of Research Compliance and Regulatory Affairs to discuss the issues, and to have their breeding colonies transferred to Managed Breeding Services.
- The IACUC office performed a PAM with the lab to discuss correctly following their approved protocol.
- The IACUC Full Committee voted to suspend the protocol and recommended that a new protocol be submitted.

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: 2022.07.01 09:21:12
-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: McCoy, Devora (NIH/OD) [E]
Sent: Friday, July 1, 2022 9:55 AM
To: robert.e.nobles@emory.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); IACUC@emory.edu
Subject: OLAW Case A3180-6J
Attachments: A3180-6J.pdf

Good morning Dr. Nobles,

Attached please find Dr. Tubbs' final response to OLAW Case A3180-6J. 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



EMORY
UNIVERSITY

Institutional Animal Care and Use Committee

June 9, 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 4/22/22. This is the final report regarding a protocol violation where an unapproved experiment study was conducted, an unapproved substance was used, a university policy was violated and animal welfare where three mice deaths occurred. The associated NIH-funded grants are 1 R01 CA255257-01A1, P50 CA217691, and R01CA200905.

Situation and Assessment

On March 7th, 2022, it was determined that the lab was performing an experimental study that was not approved in the protocol and that the lab used an unapproved virus vector in the experimental study. On March 9th, 2022, it was discovered that the lab had overcrowded mice cages which resulted in three mice deaths and had a weaning policy violation.

The corrective actions to prevent a recurrence were:

- On March 8th, vet staff assumed monitoring responsibilities of experimental animals.
- On March 9th, the lab was told to stop research with the unapproved agent, to meet with the Vice President of Research Compliance and Regulatory Affairs to discuss the issues at hand, and to have their breeding colonies transferred to Managed Breeding Services.
- On March 18th, the IACUC office performed a PAM with the lab to discuss correctly following their approved protocol.
- On April 20th, the IACUC Full Committee voted to suspend the protocol and recommended that a new protocol be submitted.

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, 6/23/2022 | 5:32 PM EDT

(b) (6)

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: Nash, Carmen <cbnash@emory.edu>
Sent: Friday, June 24, 2022 3:25 PM
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_D.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: DCO CASE

Good Friday Afternoon Dr. Tubbs,

Please review the attached final letter to OLAW regarding case file 03072022NC. If there are any questions or concerns, please feel free to contact me.

Kind regards,

(b) (6)

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A3180-6J



Initial Report of Noncompliance

By: J. Tubbs

Date: 04-22-2022

Time: 1050A

Name of Person reporting: Difficult to discern name over phone

Telephone #:

Fax #:

Email:

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?

IACUC suspended a protocol, investigation still active.

Species involved: mice

Personnel involved:

Dates and times: March 2022 (initial report to IACUC, continuing to gather details)

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 # _____