



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) 402-7065

November 22, 2019

Re: Animal Welfare Assurance
#A3180-01 (OLAW Case 50)

Dr. Todd Sherer
Interim Vice President for Research Administration
Emory University
1599 Clifton Road NE – 4th floor
Atlanta, GA 30322

Dear Dr. Sherer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 21, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Emory University, following up on an initial report on October 31, 2019. According to the information provided, OLAW understands that expired controlled drugs were used during rodent surgeries.

The corrective actions consisted of counseling the laboratory staff, stopping surgeries until in-date drugs were obtained, discarding expired drugs, and modifying the drug log to clearly identify when drugs will expire.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. In future reports, please clearly state the species involved and the type of drug (i.e., anesthetic/analgesic). Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Contact



November 21, 2019

Brent Morse DVM
Acting Director, Division of Compliance
Oversight Office of Laboratory Animal
Welfare National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Re: Emory University, Animal Welfare Assurance #A3180-01

Dear Dr. Morse,

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 email to your office on October 31, 2019. This is the final report regarding the use of expired controlled substances during surgeries. The associated NIH-funded grants are R01 CA202846-04 and U01CA19891301 .

Situation and Assessment

On July 9, 2019 during a semi-annual site inspection, it was discovered that a lab was using expired controlled substances for surgeries.

The corrective actions to prevent recurrences are detailed as follows:

1. The lab was coached on site by EU DAR vet staff about animal welfare concerns of using expired agents for surgeries.
2. The lab was told not to perform any surgeries until more controlled substances could be purchased.
3. The lab used a reverse distributor to have the expired reagent shipped back to the company for disposal.
4. The lab is currently using up to date-controlled substances for surgeries.
5. The lab has modified their drug usage log to better recognize when drugs will expire.

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 Dr. David Martin, Director, IACUC Office.

Sincerely,

(b) (6)

Todd Sherer, PhD
Interim Vice President for Research Administration
Emory University

Cc: Jeff Boatright, IACUC Chair; AAALAC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 22, 2019 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Notification Emory University (Assurance #A3180-01)

Thank you. We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Thursday, November 21, 2019 4:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Final Notification Emory University (Assurance #A3180-01)

To Whom It May Concern,

Please accept this final report of the use of expired substances for animal surgeries at Emory University (Assurance #A3180-01). If there are any questions or concerns, please feel free to contact me.

Best,

(b) (6)

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 1, 2019 7:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Notification Emory University (Assurance #A3180-01)

Thank you for this preliminary report. We will open a new case file.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, October 31, 2019 3:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Martin, W David <dwmarti@emory.edu>; (b) (6)
Subject: RE: Preliminary Notification Emory University (Assurance #A3180-01)

To Whom It May Concern,

Please accept this preliminary notification of a rodent health and welfare concern at Emory University (Assurance #A3180-01). An incident occurred where it was discovered during a semi-annual IACUC inspection that lab used expired controlled substances during surgeries. The NIH grants associated with this protocol are R01 EB020601-01A1, U01CA19891301, R01CA154846, U01CA19891301S 2 and R01CA154129A01. This investigation is ongoing and corrective actions are still being completed. A final report will be upcoming.

W. David Martin PhD, CPIA
Director, Institutional Animal Care and Use Committee (IACUC)
Phone: (b) (6)
Email: dwmarti@emory.edu
Internet: <http://www.iacuc.emory.edu/>

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