



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

October 31, 2022

Re: Animal Welfare Assurance
A3347-01 [OLAW Case 3K]

Dr. Emmanuel Giannelis
Vice Provost for Research
Cornell University - Ithaca
(b) (4) Day Hall
Ithaca, NY 14853

Dear Dr. Giannelis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 26, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Cornell University. According to the information provided, OLAW understands that on September 29, 2022, one mouse was left unattended while it was under anesthesia for surgery. Additionally, instruments for the surgery were found resting on a non-sterile pad. The mouse recovered well from anesthesia and its post-operative course was unremarkable. The associated activity was PHS funded.

Corrective and preventive actions: the principal investigator (PI) came to the procedure room and discussed the situation with the trainee regarding the requirement to remain with an anesthetized animal until recovery. Sterile technique was also reviewed with the trainee including the use of sterile drapes for resting sterile surgical instruments during the surgery. The PI also reminded lab members that animals must be attended at all times while under anesthesia and posted signs over the surgery station with this information. The PI also reviewed proper sterile technique with lab members. Finally, a veterinarian met with lab members to perform additional review of the surgical set-up and sterile surgical technique, and the lab is planning to do a surgical skills review course with a veterinarian this fall.

The prompt consideration of this matter by Cornell University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse

-S
Date: 2022.11.01 14:18:06 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

A3347-3K



Cornell University
Office of
Research Integrity and Assurance

395 Pine Tree Road, (b) (4)
Ithaca, NY 14850

(b) (6)

Email: iacuc@cornell.edu
www.oria.cornell.edu

October 26, 2022

Axel Wolff, MS, DVM, DACLAM
Deputy Director, Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Animal Welfare Assurance Number: D16-00225 (A3347-01) Cornell University – Ithaca
PHS Grant or Contract Number: NIH #5R01MH127510-02

Dear Dr. Wolff:

As Institutional Official for Cornell University's animal care and use program, I am reporting a deviation from protocol involving a mouse that occurred under our General Assurance. This issue was reported to the Institutional Animal Care and Use Committee (IACUC) at the October 20, 2022 meeting, and the IACUC agreed that the corrective actions taken were appropriate.

Explanation of the situation:

During an inspection on September 29, 2022, one mouse was left for no more than two minutes while it was under anesthesia for surgery when the surgeon/anesthetist returned a mouse to its housing room across the hall. Another lab member was in the surgery room but not directly supervising the mouse. The surgery had been completed with only wound closure remaining to be performed. Additionally, instruments for the tips-only surgery were found resting on a non-sterile pad. The mouse recovered well from anesthesia and its post-operative course was unremarkable.

Action taken by the institution:

The principal investigator (PI) was contacted and came to the procedure room and discussed the situation with the trainee regarding the requirement to remain with an anesthetized animal until recovery. Sterile technique was also reviewed with the trainee including the use of sterile drapes for resting sterile surgical instruments during the surgery. The PI also reminded lab members that animals must be attended at all times while under anesthesia, and posted signs over the surgery station with this information. The PI also reviewed proper sterile technique with lab members. Finally, a veterinarian from the Center for Animal Resources and Education (CARE) training team met with lab members to perform additional review of the surgical set-up and sterile surgical technique, and the lab is planning to do a surgical skills review course with a CARE veterinarian this fall.

If you have any questions concerning this deviation from protocol event that occurred under our General Assurance, please contact (b) (6) at (b) (6)

Sincerely,

(b) (6)

Emmanuel Giannelis
Vice President for Research and Innovation

cc:

(b) (6)

(b) (6)

AAALAC International

McCoy, Devora (NIH/OD) [E]

From: (b) (6)
Sent: Thursday, October 27, 2022 11:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Office of the Vice President for Research and Innovation;
gborkowski@aaalac.org; (b) (6)
Subject: [EXTERNAL] Adverse Event Report from Cornell University
Attachments: Incident to OLAW October 2022 Notexin Injection.docx; Incident to OLAW October 2022 Anesthetized Mouse.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Wolff,

Please see the attached reports from Cornell University's Vice President for Research and Innovation, Dr. Emmanuel Giannelis, describing an adverse event and a deviation from protocol that occurred under our General Assurance. Please let me know if you have any questions or concerns.

Sincerely,

(b) (6)

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McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, October 27, 2022 12:35 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Report from Cornell University

Good afternoon (b) (6)

Thank you for sending us these two reports and we will send official responses soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Thursday, October 27, 2022 11:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Office of the Vice President for Research and Innovation
<vp_research@cornell.edu>; gborkowski@aaalac.org; (b) (6)
(b) (6)
Subject: [EXTERNAL] Adverse Event Report from Cornell University

Dear Dr. Wolff,

Please see the attached reports from Cornell University's Vice President for Research and Innovation, Dr. Emmanuel Giannelis, describing an adverse event and a deviation from protocol that occurred under our General Assurance. Please let me know if you have any questions or concerns.

Sincerely,

(b) (6)