



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

March 25, 2022

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

Dr. Emmanuel Giannelis,
Vice Provost for Life Sciences
Cornell University
(b) (4) Day Hall
Ithaca, NY 14850

Dear Dr. Giannelis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 13, 2021 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Cornell University. According to the information provided, OLAW understands that the Cornell University Hospital for Animals anesthesia department provided anesthesia for experimental orthopedic surgery on 24 sheep. The anesthesia department did not administer intra-articular local anesthetic as outlined in the protocol. Instead, a local saphenous nerve block was used in combination with a pre-operative fentanyl patch and perioperative meloxicam. No break-through pain was observed. The discrepancy was found during an AAALAC site visit. The sheep involved in this incident were supported by NIH funding.

Corrective and preventive measures included counseling of the laboratory staff about the importance of following the approved IACUC protocol. The laboratory has submitted an amendment to include the local saphenous nerve block as an alternate method of anesthesia.

OLAW appreciates the consideration of this matter by Cornell University which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S
Digitally signed by Robyn M. Engel -S
Date: 2022.03.25 11:14:18 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, Animal Care



Cornell University
Office of
Research Integrity and Assurance

395 Pine Tree Road, Suite 320
Ithaca, NY 14850
Phone: 607-255-2214
Fax: 607-255-0758
Email: iacuc@cornell.edu
www.oria.cornell.edu

August 13, 2021

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 R44AR067533

Dear Dr. Wolff:

As Institutional Official for Cornell University's animal care and use program, I am reporting an issue of noncompliance that occurred under our General Assurance. This incident involved twenty-four sheep and occurred between May 21, 2021 and June 25, 2021. This issue was reported to the IACUC at the July 22, 2021 meeting, and the IACUC agreed that the corrective actions taken were appropriate.

Explanation of the situation:

During the AAALAC site visit, it was determined that orthopedic surgery had been performed on 24 sheep between 5/21/21 and 6/25/21. The Cornell University Hospital for Animals (CUHA) anesthesia department provided anesthesia to the animals and did not administer pre-operative or post-operative intra-articular local anesthetic as outlined in the protocol. Instead, CUHA Anesthesia staff administered a local saphenous nerve block. In the CUHA Anesthesiologist's and PI's judgement, the saphenous nerve block, in combination with the pre-op fentanyl patch and pre-op and post-op meloxicam provided adequate analgesia. No break-through pain was evident on the daily post-operative monitoring records.

Action taken by the institution:

CARE veterinary staff contacted the lab staff about the discrepancy in the experimental records and the plan as outlined in the protocol. CARE veterinary staff reminded the lab staff about the importance of following the approved IACUC protocol. The lab has submitted a protocol amendment to include local saphenous nerve block as an alternate method of anesthesia.

If you have any questions concerning this adverse event that occurred under our General Assurance, please contact

(b) (6)

Sincerely,

(b) (6)

Emmanuel Giannelis
Vice President for Research and Innovation

cc:

(b) (6)

(b) (6)

AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 11, 2022 4:01 PM
To: Walker, Keri (NIH/NIMH) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Missing response to a Cornell University Report of Noncompliance

Thank you Keri, we'll take it from here.

(b) (6)

Axel Wolff

From: Walker, Keri (NIH/NIMH) [E] <keri.walker@nih.gov>
Sent: Friday, March 11, 2022 3:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Missing response to a Cornell University Report of Noncompliance

Hello!

See below and attached 😊

Best,
Keri

Keri Walker

Grants Management Specialist
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892-9605
Email: keri.walker@nih.gov
Office: (301) 402-8329



From: (b) (6)
Sent: Friday, March 11, 2022 3:28 PM
To: Walker, Keri (NIH/NIMH) [E] <keri.walker@nih.gov>
Cc: (b) (6)
Subject: Missing response to a Cornell University Report of Noncompliance

Dear Keri,

I apologize for not contacting you sooner, but we seem to be missing an official response to an incident report that we submitted in August. It's entirely possible that we misfiled the response. Would you mind sending us the response again?

Many thanks,
(b) (6)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, August 18, 2021 7:31 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Cornell University Report of Noncompliance

Thank you for these reports, (b) (6) We will send responses soon.
Axel Wolff

From: (b) (6)
Sent: Monday, August 16, 2021 10:05 AM
To: olawdco@mail.nih.gov
Cc: (b) (6) Office of the Vice President for Research and Innovation <vp_research@cornell.edu> (b) (6)
Subject: Cornell University Report of Noncompliance

Dear Dr. Wolff,

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

Sincerely,

(b) (6)