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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

September 15, 2021

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

Re: Animal Welfare Assurance A3347-01 [OLAW Case 3D)

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 instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Cornell University. According to the information provided, OLAW understands that during the AAALAC site visit, it was determined that lab members were not using sterile instruments as they were disinfecting glass window implants with 70% ethanol and prepping the skin of the surgical site with 70% ethanol only. The IACUC protocol states that Animal Care and Use Procedure (ACUP) 201 will be followed for pre-surgical, intra-operative and post-operative care. ACUP 201 states that " Alcohol immersion will not sterilize equipment." The ACUP also instructs individuals that an antiseptic soap solution must be used in tandem with a rinse solution for the surgical site preparation. No adverse events appear to have resulted from the 70% ethanol use. The studies were supported by NSF funding.

As a corrective measure, the Center for Animal Resources and Education (CARE) veterinary staff contacted the lab to remind them of compliance with ACUP 201 and that aseptic technique must be used during future surgeries. Lab members will familiarize themselves with the IACUC protocol and referenced ACUPs. Lab members performing surgery must take the Aseptic Technique for Rodent Survival Surgery module on the AALAS learning library if not previously completed. CARE staff will work with the lab to establish sterilization protocol for surgical materials.

OLAW appreciates the prompt consideration of this matter by Cornell University which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare

CC: IACUC contact

A3347-3D



395 Pine Tree Road, Suite 320 Ithaca, NY 14850 Phone: 607-255-2214 Fax: 607-255-0758 Email: <u>iacuc@comell.edu</u> www.oria.comell.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: NSF DBI-1707312

Dear Dr. Wolff:

As Institutional Official for Cornell University's animal care and use program, I am reporting an issue of noncompliance involving mice that occurred under our General Assurance. 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 lab members were not using sterile instruments, were disinfecting the glass windows implants with 70% ethanol, and were prepping the skin of the surgery site with 70% ethanol only. The IACUC protocol states that Animal Care and Use Procedure (ACUP) 201 will be followed for pre-operative, surgical, and post-operative care. ACUP 201 states "Alcohol immersion will not sterilize equipment". It also instructs that an antiseptic soap solution must be used in tandem with a rinse solution for preparation of the surgical site. No adverse events appear to have resulted from the use of 70% ethanol.

Action taken by the institution:

The lab was contacted by Center for Animal Resources and Education (CARE) veterinary staff and reminded of the principles outlined in ACUP 201. The lab was instructed that they must use aseptic principles during future animal surgeries. Lab members will familiarize themselves with the IACUC protocol before starting work on animal procedures and will also familiarize themselves with the ACUPs referenced in the IACUC protocol. Lab members that will perform animal surgeries must take the Aseptic Technique for Rodent Survival Surgery module on the AALAS Learning Library if previously not completed. CARE veterinary staff will work with the lab to establish a sterilization protocol for surgical materials.

If you have any questions concerning this adverse event that occurred under our General Assurance, please contact Christine Bellezza, Director of Research Assurance in the Office of Research Integrity and Assurance at cab37@cornell.edu.

Sincerely, (b) (6)

(b) (6)

Emmanuel Giannelis Vice President for Research and Innovation

cc:

C. Bellezza AAALAC International

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Wednesday, August 18, 2021 7:31 AM
То:	Christine A. Bellezza
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Cornell University Report of Noncompliance

Thank you for these reports, Dr. Bellezza. We will send responses soon. Axel Wolff

From: Christine A. Bellezza <cab37@cornell.edu> Sent: Monday, August 16, 2021 10:05 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 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, Chris

Christine A. Bellezza, DVM Director of Research Assurance Office of Research Integrity and Assurance (ORIA) Cornell University / (b) (4) 395 Pine Tree Rd / Ithaca, NY 14850 T (b) (6) / Email <u>cab37@cornell.edu</u> www.oria.cornell.edu