



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

August 23, 2021

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

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. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Cornell University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states that during the AAALAC site visit, it was determined that the lab had been using 70% ethanol to disinfect equipment for surgical procedures. This finding was not consistent with the protocol, which referenced the Animal Care and Use Procedure (ACUP) 201 for rodent surgery (which states "Alcohol immersion will not sterilize equipment"). The protocol also notes that surgical instruments and materials will be sterilized via autoclave, ethylene oxide, or immersion in Cidex OPA. While the protocol describes the use of tissue glue, several non-pharmaceutical grade cyanoacrylate adhesives were present in the lab. The principal investigator (PI) explained that different products have different viscosities, and the lab used the product best suited for the different surgeries. The report states no adverse events were identified from the use of 70% ethanol and non-pharmaceutical grade cyanoacrylate adhesives.

In response to the findings, the Center for Animal Resources and Education (CARE) veterinary staff reviewed the issues with the PI and some lab members. The lab terminated the use of 70% ethanol. Also, materials that cannot be autoclaved will be sterilized using Cidex immersion. Lastly, an amendment was submitted to provide justification for the use of non-pharmaceutical grade cyanoacrylate adhesives.

It is noted that this project is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the Cornell 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
Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.08.23 15:27:01
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cc: IACUC Contact



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 AG049952

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 an AAALAC site visit, it was realized during conversation with lab staff that the glass windows used in the surgical procedures are disinfected with 70% ethanol. The lab's approved IACUC protocol references Animal Care and Use Procedure (ACUP) 201 for rodent surgery (which states "Alcohol immersion will not sterilize equipment"), and the IACUC protocol states that surgical instruments and materials will be sterilized via autoclave, ethylene oxide, or immersion in Cidex OPA. The protocol also mentions tissue glue such as Vetbond for wound closure. Vetbond was present in the procedure space, as were several non-pharmaceutical grade cyanoacrylate adhesives. The PI justified the use of non-pharm cyanoacrylate in that different products have different viscosities, and his lab uses the product that works best for the different surgeries. No adverse events appear to have resulted from the use of 70% ethanol or non-pharmaceutical grade cyanoacrylate adhesives.

Action taken by the institution:

Center for Animal Resources and Education (CARE) veterinary staff discussed these issues with the PI and some of his staff. The lab has discontinued use of 70% ethanol as a chemical sterilant. Materials that cannot be autoclaved will be sterilized using Cidex immersion. An amendment will be submitted that provides a justification for the use of non-pharmaceutical grade cyanoacrylate adhesives.

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)

Emmanuel Giannelis
 Vice President for Research and Innovation

cc:

(b) (6)

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
To: 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
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