



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

December 5, 2022

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

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

Dear Dr. Giannelis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 21, 2022 letter reporting an adverse event 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 an adverse event occurred with respect to unexpected mortality in chinchillas following inoculation with bacteria. The final report states on September 29, 2022, one chinchilla was found dead 3 days post-inoculation. On October 6, 2022, another chinchilla was found dead 7 days post-inoculation with *Streptococcus pneumoniae*. It is stated the animals did not exhibit clinical signs of disease prior to death. It was determined the animals received higher than expected doses due to the potency of a new batch of bacteria grown in the lab. Per the report, three other chinchillas were infected with the same dose of bacteria and did not display any adverse effects.

Gross necropsy findings revealed potential septic infection. In response to the incident, the growth curve of fresh frozen stocks will be carefully measured prior to *in vivo* inoculation. The IACUC has reviewed the matter and agreed the corrective actions were appropriate.

It is noted that this research is supported by PHS funding. 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.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2022.12.05 14:43:31 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations



Cornell University
Office of
Research Integrity and Assurance

Ithaca, NY 14850
Email: iacuc@cornell.edu
www.oria.cornell.edu

November 21, 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 R21DC019184

Dear Dr. Wolff:

As Institutional Official for Cornell University's animal care and use program, I am reporting an adverse event involving two chinchillas that occurred under our General Assurance. This issue was reported to the IACUC at the November 17, 2022 meeting, and the IACUC agreed that the corrective actions taken were appropriate.

Explanation of the situation:

On September 29, 2022 one chinchilla was found deceased 3-days post-inoculation and on October 6, 2022 a second chinchilla was found deceased 7-days post-inoculation with *Streptococcus pneumoniae*. These chinchillas did not display overt clinical signs of disease prior to death. It was determined that these chinchillas received higher-than-expected doses due to the potency of a new batch of bacteria grown in the lab. Three other chinchillas had been infected with the same dose of bacteria and did not display any adverse effects.

Action taken by the institution:

Gross necropsies were performed and revealed possible septic infection. Moving forward, the growth curve of fresh frozen stocks will be carefully measured (in duplicate) before proceeding with *in vivo* inoculation.

If you have any questions concerning this adverse 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)

AAALAC International

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 22, 2022 7:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Reports from Cornell University

Good morning (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: Monday, November 21, 2022 4:28 PM
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) accredit@AAALAC.org
Subject: [EXTERNAL] Adverse Event Reports 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 adverse events that occurred under our General Assurance. Please let me know if you have any questions or concerns.

Sincerely,
(b) (6)