



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

May 4, 2022

Re: Animal Welfare Assurance
A3347-01 [OLAW Case 31]

Dr. Emmanuel Giannelis
Vice Provost for Life Sciences
Cornell University
(b) (4) Biotechnology Building
Ithaca, NY 14853

Dear Dr. Giannelis,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 29, 2022 letter reporting an adverse event involving a sheep at Cornell University. According to the information provided, OLAW understands that sheep were being used in a study to implant a carotid artery graft and in four of the animals the procedure was successful. In the last animal the graft failed after being allowed to cure for only 36 hours rather than 72. The graft failure resulted in hemorrhage which could not be successfully stopped.

The immediate action taken in response was to apply neck pressure and to return the animal to the surgery room, but then a decision was made to euthanize the sheep. Additional surgeries were stopped until the graft failure was addressed. It was determined that the composition of the failed graft was more fragile than the others and less resilient to the suturing. The preventive measures consisted of only using the graft that was cured for a longer time, fusing the outer layers of the graft, and performing suture tests on the grafts prior to use in animals.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals and, unless informed to the contrary, we assume that the protocol was amended to reflect the proposed preventive measures.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Cornell University
Office of
Research Integrity and Assurance

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

(b) (6)

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April 29, 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 1R01HL159427-01

Dear Dr. Wolff:

As Institutional Official for Cornell University's animal care and use program, I am reporting an adverse event involving one sheep that occurred under our General Assurance. This issue was reported to the IACUC at the April 21, 2022 meeting, and the IACUC agreed that the corrective actions taken were appropriate.

Explanation of the situation:

A carotid artery graft was implanted in five sheep, and during recovery a graft in one of the sheep failed. Pressure was immediately applied to the neck to reduce bleeding and the sheep was taken back to the operating room. The surgical team examined the sheep and confirmed that the graft failed. The first four sheep had grafts that were cured for 72 hours, and all recovered without any incident. The last sheep received a graft that only cured for 36 hours in order to produce a softer and more elastic graft. A decision was made to implant the same graft that was used in the first four sheep. Following the second graft implant, as this sheep tried to stand during recovery, hemorrhage was once again noted and a decision was made to euthanize this sheep.

Action taken by the institution:

Surgery on other sheep was cancelled until the reason for the graft failure could be determined and addressed.

One key difference between the successful surgeries and the failed surgery is that the graft was of a different composition, and the softer material used was less resilient to repeated punctures during suturing. Moving forward, three changes will be implemented. First, the more robust material that is cured for 72 hours will be used. Second, the fibers will be fused in the outer layer to prevent fibers at the graft's edge from unraveling. Finally, suture tests will be performed on every type of graft prior to use in live animals.

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: Monday, May 2, 2022 7:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Report from Cornell University

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Saturday, April 30, 2022 8:06 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>; (b) (6)
Subject: [EXTERNAL] Adverse Event Report from Cornell University

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,

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

Sincerely,

(b) (6)