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**To:** [Dana - APHIS Miller \(dana.miller2@usda.gov\)](#); [Michael F - APHIS Neafsey \(michael.f.neafsey@usda.gov\)](#)  
**Subject:** FW: OLAW Case A3597-2U  
**Date:** Wednesday, June 5, 2019 2:27:00 PM  
**Attachments:** [2716\\_001.pdf](#)

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fyi

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**From:** Ward, Joan (NIH/OD) [E] [<mailto:wardjoa@od.nih.gov>]  
**Sent:** Wednesday, June 5, 2019 12:09 PM  
**To:** [fred.king@mail.wvu.edu](mailto:fred.king@mail.wvu.edu)  
**Cc:** (b) (6) Gibbens, Robert -  
APHIS <[robert.m.gibbens@usda.gov](mailto:robert.m.gibbens@usda.gov)>  
**Subject:** OLAW Case A3597-2U

Dear Dr. King,

Attached please find Dr. Axel Wolff's final response to OLAW Case A3597-2U.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,  
Joan

*Joan Ward  
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June 5, 2019

Re: Animal Welfare Assurance  
#A3597-01 (OLAW Case 2U)

Dr. Fred King  
Vice President for Research  
West Virginia University  
886 Chestnut Ridge Road, (b) (4)  
P O Box 6216  
Morgantown, WV 26506-6103

Dear Dr. King,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 3, 2019 letter responding to my April 29, 2019 request for information about sheep studies conducted at West Virginia University. Complications occurred in some of the procedures and Stop Animal Exploitation Now (SAEN) stated that the problems should have been reported to OLAW. According to the information provided, OLAW understands the following:

- 1) June 26, 2017 incident report: a sheep was being dosed with an experimental drug under an approved protocol and experienced an adverse reaction which caused a seizure. The veterinary technician was notified but the sheep died. The experimental drug had been given for a longer period of exposure than before, but all activities had been conducted in accordance with the protocol. The protocol was amended to lower the dose of the drug, to increase animal monitoring, and to have more veterinary involvement in the study. No further problems occurred with the use of the drug. The matter had not been reported to OLAW because the Institutional Animal Care and Use Committee (IACUC) determined that there had been no protocol violation or negligence.
- 2) August 8, 2018 incident report: another sheep on the study exhibited increasing body temperature and developed seizures after receiving another experimental drug. The sheep was under veterinary care and received antibiotics and a fever reducing drug. Following the seizures, the animal was euthanized at the direction of the veterinarian and in accordance with the humane endpoints described in the protocol. The cause of illness could not be determined. The matter had not been reported to OLAW because the IACUC determined that there had been no protocol violation or negligence. No other events of this type have recurred.
- 3) October 25, 2018 incident report: another sheep on the study underwent surgery to remove the ovaries and experienced bleeding which was stopped before closing the incision. Because the animal became lethargic and anemic, the veterinarian directed an exploratory surgery to assess any internal bleeding. The sheep died under anesthesia. The IACUC determined that there had been no mistakes made or noncompliance, but the protocol was amended to include use of a tissue fusion system. The research staff was trained on use of the system which allows for quicker surgeries and adhesion of tissue. The new equipment has been successfully used on subsequent surgeries. The matter had not been reported to OLAW because the IACUC determined that there had been no protocol violation or negligence.

Based on its assessment of these explanations, OLAW concurs that while adverse events did occur, they had been handled appropriately and refinements were made. There was no evidence of poor surgical technique, no lack of aseptic technique, no improper animal handling, no inadequate veterinary care, and no participation of unqualified personnel. As such, there was no violation of the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals and no need for a report to OLAW. Thank you for your prompt and thorough response. We will provide this assessment to SAEN and hereby close this investigation.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Animal Welfare Program Director  
Robert Gibbens, D.V.M., USDA-APHIS-AC