FYI

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From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Thursday, May 30, 2019 12:07:00 PM
To: 'chris.keane@wsu.edu'
Cc: iacuc@wsu.edu; Gibbens, Robert - APHIS
Subject: OLAW Case A3485-U

Dear Dr. Keane,

Attached please find Dr. Axel Wolff's final response to OLAW Case A3485-U

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

## Regards,

Joan

Joan Ward Program Specialist Office of Laboratory Animal Welfare National Institutes of Health 6705 Rockledge Dr., Suite 360 Bethesda, MD 20892 301-496-7163 wardjoa@od.nih.goy



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

May 28, 2019

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 Facsimile: (301) 402-7065

## Re: Animal Welfare Assurance A3485-01 [OLAW Case U]

Dr. Christopher J. Keane Vice President for Research Washington State University P.O. Box 646525 Pullman, WA 99164

Dear Dr. Keane,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 24, 2019 letter responding to my April 29, 2019 request for information regarding an allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Washington State University. Specifically, Stop Animal Exploitation Now (SAEN) stated that a bone study in rabbits was suspended by the Institutional Animal Care and Use Committee (IACUC) but that this action was not reported to OLAW. According to the information provided, OLAW understands the following:

- 1) An IACUC approved bone implant study was conducted in rabbits between July 25, 2018 and August 2, 2018.
- 2) This study was supported by NIH. The grant number was provided.
- 3) The IACUC did not suspend or terminate the study. The Principal Investigator, in consultation with the Attending Veterinarian, euthanized one cohort of rabbits prior to the planned endpoint in order to determine the cause of the unexpected bone fractures.
- 4) Although there were adverse study outcomes, there was no noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals*.
- 5) Because there was no suspension or termination, no report needed to be made to the funding component.
- 6) Unexpected complications occurred with the study rabbits including bone fractures, incisional swelling, infection, seizures, and migrating implants. The rabbits were treated by the veterinary staff but due to the health issues, the remaining animals were euthanized prior to the planned endpoint. Samples were taken for histology and an adverse event report will be submitted to IACUC once all data have been gathered.

Based on its assessment of these explanations, OLAW has a better understanding of the facts surrounding this case. I will explain to SAEN why no report to OLAW was necessary. Please do provide an update regarding possible reasons for the unexpected problems encountered in this study. Thank you for keeping OLAW apprised on this matter.

Page 2 – Dr. Keane May 28, 2019 OLAW Case A3485-U

Sincerely,

(b) (6)

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

cc: IACUC Chair Robert Gibbens, D.V.M., USDA-APHIS-AC