

From: [Ward, Joan \(NIH/OD\) \[E\]](#)
To: ["chris.keane@wsu.edu"](mailto:chris.keane@wsu.edu)
Cc: iacuc@wsu.edu; [Gibbens, Robert - APHIS](#)
Subject: OLAW Case A3485-U
Date: Wednesday, May 1, 2019 1:03:54 PM
Attachments: [1931_001.pdf](#)

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
6700B Rockledge Dr., Suite 2500
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301-496-7163
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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) 402-7065

April 29, 2019

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) received an allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Washington State University (WSU) from Stop Animal Exploitation Now (SAEN). The allegation stated that the Institutional Animal Care and Use Committee suspended an activity with rabbits but failed to report this to OLAW. The incident being cited concerns a bone surgery study in rabbits which took place from July 25, 2018 to August 2, 2018. From the supporting documentation provided by SAEN it appears that bilateral bone implants were being placed in the distal femur which resulted in fractures and required euthanasia of two animals. Problems occurred in the other rabbits as well. SAEN obtained a copy of the IACUC minutes from September 26, 2018 (presumably through a Freedom of Information Act request) which states that the project has been terminated. SAEN has interpreted this action as being a suspension and has therefore contacted OLAW with this complaint and feels that the matter should have been reported to this Office as being noncompliant with IV.F.3.c of the PHS Policy.

Please direct the IACUC, avoiding any conflicts of interest, to address this matter and provide answers to the following questions:

- 1) Was a bone implant study conducted in rabbits at WSU during the time period noted?
- 2) If so, was the study funded by PHS, NIH, NSF, or other federal entity under OLAW jurisdiction? If confirmed please provide the grant number.
- 3) Did the IACUC take any action with this study such as suspension or termination? Was any action taken in accordance with IV.C.6 of the PHS Policy?
- 4) Did any IACUC actions or noncompliance occur with the rabbit study which should have been reported to OLAW? See also NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals: "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals." If so, why was no report made to OLAW?
- 5) If this project was funded by NIH, was the termination reported to the funding component?
- 6) Provide any other pertinent information regarding the rabbit study.

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April 29, 2019
OLAW Case A3485-U

Please provide the requested information by **May 27, 2019**. Feel free to contact me with any questions.

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

From: [Ward, Joan \(NIH/OD\) \[E\]](#)
To: ["chris.keane@wsu.edu"](mailto:chris.keane@wsu.edu)
Cc: iacuc@wsu.edu; [Gibbens, Robert - APHIS](#)
Subject: OLAW Case A3485-U
Date: Thursday, May 30, 2019 2:07:05 PM
Attachments: [2519_001.pdf](#)

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
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May 28, 2019

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.

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