



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

January 31, 2020

Re: Animal Welfare Assurance  
#A3213-01 (OLAW Case 2F)

Dr. Kathryn A. Moler  
Vice Provost and Dean of Research  
Stanford University  
(b) (4) Panama Mall  
Stanford, CA 94305-2061

Dear Dr. Moler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Stanford University. According to the information provided, OLAW understands that tumors were removed from a rodent without the use of analgesia. The surgery had not been described in the protocol.

The corrective actions consisted of the Principal Investigator counseling the laboratory staff to follow the protocol and requiring the staff to undertake retraining. The laboratory is to examine all animal activities and amend the protocol if any unapproved procedures are identified. The laboratory must submit surgical records from the next ten survival surgeries to the Research Compliance Office.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please remember to specifically state the species involved in a reportable event. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



## STANFORD UNIVERSITY

KATHRYN A. MOLER  
VICE PROVOST  
DEAN OF RESEARCH

**Confidential**

December 18, 2019

Brent Morse, DVM, DACLAM  
Director of Compliance Oversight  
Office of Laboratory Animal Welfare  
Division of Compliance Oversight  
National Institutes of Health  
6705 Rockledge Drive  
RKL 1, Suite 360 MSC 7982  
Bethesda, MD 20892-7982

Dear Dr. Morse:

As Stanford University's authorized institutional official under its PHS Assurance (Animal Welfare Assurance #A3213-01), I am writing to notify OLAW of a reportable incident as defined in PHS Policy IV.F.3.

IACUC determination	Serious noncompliance
Funding	NIH awards AR046786, AR070361, AR054780, and CA211793

**Description:**

At a convened meeting, the IACUC discussed an allegation of noncompliance involving a rodent. The laboratory performed a survival surgical procedure not described in the protocol, which involved the removal of several large tumors without appropriate analgesia. The APLAC determined that this incident met the definition of serious noncompliance as it resulted in actual harm to the animal.

A preliminary report of this incident was provided to OLAW on July 22nd, 2019, via a telephone call from the Associate Director of the Institutional Animal Care and Use Program, Research Compliance Office.

**IACUC Determination:**

An IACUC subcommittee met to review these concerns and the corrective actions that had been taken. Based on its review, the subcommittee recommended that this incident be classified as serious noncompliance as it constituted a failure to adhere to the PHS "Policy on Humane Care and Use of Laboratory Animals".

At the convened meeting, the IACUC discussed the subcommittee's recommendation. A motion to accept this finding was made, seconded and approved. The APLAC also recognized that the PI has been performing animal work under this protocol for more than a decade without any noted deviations. A determination memo from the IACUC Chair has been sent to the PI.

408 Panama Mall • Stanford, California 94305-2061  
Tel (650) 723-0977 • Fax (650) 725-1653 • kmoler@stanford.edu

Dr. Brent Morse  
December 18, 2019

**Corrective Actions and Follow up:**

- Once made aware of this incident, the PI met with all animal users in the laboratory to direct them on the importance of following the approved protocol and all relevant guidelines for animal use at Stanford.
- The IACUC requests mandatory training for existing and future lab staff (specifically for protocol compliance) and documentation of training attendance.
- The IACUC requests that the lab carefully evaluate their experimental plans, and if necessary, revise their protocol to include any procedures that have not been included in the approved protocol.
- The IACUC requests that the lab submit surgical records from their next 10 survival surgeries for evaluation by the Research Compliance Office.

**Concluding Remarks:**

The IACUC has carefully reviewed this incident with all parties involved. Stanford believes that a recurrence of an incident of this nature is unlikely as all lab members have received appropriate training, and the PI and laboratory staff are committed to preventing a future occurrence. Please contact me or (b) (6) (b) (6) if you have any questions or need additional information.

Sincerely,

(b) (6)

cc: Kathryn Bayne, MS, PhD, DVM, DACLAM, DACAW, CAAB, Global Director AAALAC International

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, January 24, 2020 7:29 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Notification for PHS Assured Institution #A3213-01

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

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Thursday, January 23, 2020 5:41 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** OLAW Notification for PHS Assured Institution #A3213-01

Dear Dr. Morse -

On behalf of Stanford University's Institutional Official, I am writing to notify OLAW of a serious noncompliance. Please see the attached document.

Feel free to contact me if you have any questions or concerns.

Best,  
(b) (6)

(b) (6)

\*\*\*As part of an on-going effort to improve our services, we invite you to complete a post-approval survey regarding your APLAC experience.\*\*\*

Please use this link: [https://stanforduniversity.qualtrics.com/jfe/form/SV\\_e5694IPKNqUvDM1](https://stanforduniversity.qualtrics.com/jfe/form/SV_e5694IPKNqUvDM1)