



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

August 17, 2018

Re: Animal Welfare Assurance
A3229-01 [OLAW Case K]

Dr. Cynthia Sagers
Vice President for Research
Oregon State University – Corvallis
(b) (4) Kerr Administration Building
Corvallis, Oregon 97331-2140

Dear Dr. Sagers,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 15, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Oregon State University, following up on an initial telephone report on April 27, 2018. According to the information provided, OLAW understands that activities continued on a surgical sheep study after the protocol had expired. Neither the surgeon nor the anesthetist were listed on the protocol, the surgical records were incomplete or unavailable, controlled drug use and acquisition was not compliant with institutional policies, and the controlled drug log was not completed. It was later discovered that two additional sheep surgeries had been conducted under the expired protocol by the same team.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) suspending the surgical privileges of the surgeon and withholding the approval of a newly submitted protocol to replace the expired one. The surgeon attended a professional IACUC conference, discussed the conference information with the IACUC office, and submitted a letter of understanding regarding the institutional animal care and use program to the IACUC. The IACUC initially lifted the suspension, but following discovery of the two additional surgeries, the IACUC suspended the surgeon's animal use privileges for one year and informed the investigators involved that no data collected during the period the protocol was expired could be confirmed as having been approved by the IACUC. A protocol covering this study was submitted by the person who improperly acquired the controlled drugs and is under IACUC review. The funding for the study was from a subaward from a collaborating institution, which has been notified about the noncompliance.

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 IACUC to comply with the PHS Policy and recommends that upon continuation of this study, the laboratory is placed under enhanced post-approval monitoring. Please continue investigating the funding chain to ensure that no PHS funds were spent on any animal activity following expiration of the protocol and contact (or have the primary grantee/collaborator contact) the NIH funding component to report the incident and reconcile the financial aspects of this grant. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

(b) (6)

August 15, 2018

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
olawdco@mail.nih.gov

Re: Final Report

Dear Dr. Wolff:

In accordance with our Animal Welfare Assurance A3229-01, we provide this final report regarding noncompliant survival surgeries and tissue collection. This incident was first reported to Dr. Axel Wolff, OLAW, on April 27, 2018 via a telephone call by the IACUC administrator. The noncompliant activities appear to be associated with a collaboration and subaward from Oregon Health Sciences University (OHSU) to OSU involving NIH RR14270, ending in FY 2017.

An IACUC protocol describing survival surgeries approved for reproductive and fetal tissue collection in ewes expired on 11/03/2017. No renewal protocol was submitted, as the principal investigator on the protocol was discontinuing involvement in the research program. Another faculty member with a DVM performed surgeries on three ewes, using a student as the anesthetist, just prior to the protocol expiration date. Neither the surgeon faculty member (SFM) nor the student anesthetist were on the IACUC protocol. Post-surgical treatments and recovery monitoring continued past the protocol expiration date, and medical/ surgical/ anesthesia records were either incomplete or unavailable.

In addition, the SFM acquired and used DEA-controlled drugs for these procedures noncompliantly, per the approved IACUC protocol, home department procedures, and contrary to communications with the Veterinary Teaching Hospital (VTH) Pharmacy Director. The SFM asked another faculty member with VTH privileges to provide the drugs needed to perform surgeries because they could not be ordered and received according to approved procedures before the surgeries needed to be performed. The VTH faculty member who provided the SFM with the requested drugs did so against VTH Pharmacy policy. Further, DEA drug use logs for these bottles were not completed at the time of use.

Around the time of this incident, the SFM had submitted, as the PI, an IACUC protocol. This protocol was very similar to the one that had expired, and it was called to full committee review (FCR) for further discussion.

The IACUC reviewed the incident information and voted to withhold approval of the SFM's protocol under review; and suspend the SFM's ability to perform surgery on any Animal Care and Use Program animals at the institution, pending appropriate demonstration from the SFM to the IACUC about the importance of their role and responsibilities in the Program. The SFM attended a 1-day regional IACUC conference on February 27th, then met with the IACUC office to review conference content and discuss related institutional policies, procedures, and expectations for Program investigators. The SFM submitted a letter to the committee describing improved understanding of the institutional Program, responsibilities associated with survival surgeries and training students, and lawful use of DEA-controlled drugs.

At the March 15, 2018 convened meeting, the IACUC reviewed the above response and voted to lift the

SFM suspension and institute probation for one year, noting that the IACUC would consider more significant suspension proposals if violations were to occur.

On March 20, 2018, the IACUC learned that two additional ewe surgeries were performed by the same people under the same protocol, after the protocol expired on 11/03/2017. Both surgeries were completed on 11/09/2017 and had not been previously disclosed to the IACUC, despite an email from the IACUC to the SFM sent on the same day (11/09/2017) requesting copies of animal anesthesia and surgery records for all procedures performed or directed over the past 30 days. Additional records were again requested from the SFM, and the new information was discussed at the following convened meeting on April 11, 2018. The IACUC voted to suspend the SFM's ability to oversee or participate in any part of live animal surgery, anesthesia, perioperative care or DEA-regulated drug use for a minimum period of one year. The original PI and SFM were also notified that any data resulting from tissues collected noncompliantly cannot be represented as "IACUC-approved". The collaborating institution's IACUC office was also contacted about the noncompliance. It was not clear whether subaward funding had been used to purchase and/or support the animals used for the procedures.

The VTH faculty member involved with noncompliant drug procurement (described above) recently submitted, as the PI, a renewal protocol to the IACUC for this work. Review is pending.

Our institution is committed to protecting the welfare of animals used in our Program and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me, the IACUC Administrator, or IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

DocuSigned by:
(b) (6)

C0709173905C46F...
Cynthia Sagers, Ph.D.

Vice President for Research and Institutional Official
Oregon State University

8/15/2018 | 15:16:35 PDT

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 16, 2018 12:04 PM
To: IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report

Thank you for submitting this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: IACUC [mailto:IACUC@oregonstate.edu]
Sent: Wednesday, August 15, 2018 6:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final Report

Hello Dr. Wolff,

Please see the attached final report, signed by our Institutional Official.

If there are additional questions, I would be happy to assist or route, as indicated.

Thank you for your time,

(b) (6)





Initial Report of Noncompliance

By: aw

Date: 4/27/18

Time: 11:15

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: OREGON STATE U

Assurance number: A3329

Did incident involve PHS funded activity? yes (subcontract)

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

2 people not on protocol did anesthesia + surgery
Some surgery done after protocol expired.
Improper use of controlled drugs.

Species involved: sheep

Personnel involved:

Dates and times:

Animal deaths:

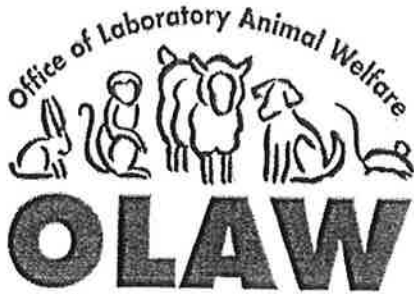
Projected plan and schedule for correction/prevention (if known): _____

Suspend person, send to conference. Suspend faculty
person for 1 year. I have will monitor study closely.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____



Division of Compliance Oversight

Record of Call for Case # A3229-K

Date & Time	Message	Initials
8-10-18 2:50pm	Left voice message for (b) (6) to please call regarding status of final or interim report.	cr v. d. s.
8-10-18 3:12pm	(b) (6) called and this case has been resolved. Final report will be submitted in near future.	cr v. d. s.