



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

October 31, 2018

Re: Animal Welfare Assurance
#A3518-01 [OLAW Case 1Q]

Randolph W. Hall, Ph.D.
Vice Provost of Research
University of Southern California
3720 South Flower St., Room [REDACTED]
Los Angeles, CA 90089-0706

Dear Dr. Hall,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 15, 2018 letter, received in our office October 29, 2018, reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Southern California. Your letter supplements the information provided in the initial telephone report from Dr. Casebolt on May 31, 2018. According to the information provided it is understood that on March 16 and April 4, 2018 the institution was notified of incidents associated with the same lab. These incidents included unapproved survival surgery on mice and inadequate post-operative care including not providing consistent post-surgical analgesia and not removing sutures or wound clips on time. The April 4th incident also included inadequately shaved surgical site on the animals head. The mice were subsequently euthanized as a result of these incidences. One related protocol was supported by PHS funds.

The IACUC required the PI to develop a SOP for all surgical procedures, distribute it to all laboratory staff members and attach it to the IACUC protocols. The PI and all laboratory staff members were required to undergo retraining and were not allowed to work with animals, other than non-surgical procedures, until the training was completed. The IACUC also required that the protocols be updated with all proposed surgical procedures and post-approval monitoring of the procedures. The PI was also required to submit a plan to prevent future noncompliance.

OLAW appreciates the consideration of these matters by the University of Southern California, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate these incidents, correct the non-compliances, and prevent recurrence. OLAW concurs that the incidents warranted reporting. Please be sure that costs for unauthorized surgeries are not charged to the grant. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



October 15, 2018

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse:

This is to report noncompliance of animal use activities at the University of Southern California (animal welfare assurance number D16-00320/A3518-01). Dr. Donald Casebolt provided a preliminary report to you on May 31, 2018. One of the three IACUC protocols for this work was associated with Public Health Service funding, proposal number NCI 11767290 (project end date June 30, 2020).

Laboratory staff members performed unapproved survival surgical procedures on mice and failed to provide adequate post-operative care and documentation for such. On March 16, 2018, the laboratory was reported to Department of Resources veterinarians for multiple instances of neglecting to remove sutures and wound clips within 14 days of surgery and not properly using required post-operative cage card records. Upon investigation, the laboratory was found to be performing unauthorized, survival, tumor removal surgeries. Additionally, in a meeting with the Department of Animal Resources veterinarians, laboratory members admitted that they had not provided consistent analgesia treatment following all survival surgeries as outlined in the approved protocol.

On April 4, 2018, a mouse was noted in a cage without any post-operative care record, that had sutures and a mass on an inadequately shaved surgical site on its head. Cranial implantation surgery was not approved on the protocol and analgesia was not documented on the cage. The animals were euthanized as a result of these incidences. Also, one of the laboratory protocols was flagged in 2015 for post approval monitoring for survival surgery, which was never conducted because the laboratory staff members did not contact a veterinarian as instructed when the protocol was approved.

The following corrective actions were taken by the IACUC with respect to these incidents:

The IACUC reviewed the incidents at its April 25, 2018 meeting of a full committee with a quorum in attendance. The committee voted to require a written response from the principal investigator with a plan to prevent future noncompliance in the

laboratory. The IACUC also required the PI to develop a Standard Operating Procedure (SOP) for all surgical procedures, distribute the document to all laboratory members, and attach the documents to all of the IACUC protocols.

All members of the laboratory on the animal protocols, including the Principal Investigator were required to undergo re-training. All members of the laboratory were not allowed to conduct any animal research procedures except breeding colony maintenance and other non-surgical procedures until the successful completion of this training. The IACUC also required that the protocols be updated with all proposed surgical procedures and with post approval monitoring of the procedures.

The Principal Investigator provided a complete response to all of the required items on July 18, 2018. The written response from the Principal Investigator, protocol amendments, and training documentation for the staff members were reviewed at the full IACUC meeting on July 25, 2018. The response was complete and deemed acceptable by the IACUC. To date there have been no other instances of noncompliance in this principal investigator's laboratory.

Should you have any questions about these incidents or the corrective actions outlined above, please contact Dr. Donald Casebolt at (b) (6)

Sincerely,

(b) (6)

Randolph W. Hall, Ph.D.
Vice President of Research

CC: Dr. Brett Lund
Dr. Donald Casebolt

(b) (6)

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(b) (6)

(b) (6)



Initial Report of Noncompliance

By: *ASM*Date: *5/31/18*Time: *3:30*

Name of Person reporting: *Don Casebolt*
 Telephone #: [REDACTED] (b) (6)
 Fax #: [REDACTED]
 Email: [REDACTED]

Name of Institution: *USC*
 Assurance number: *A3518*

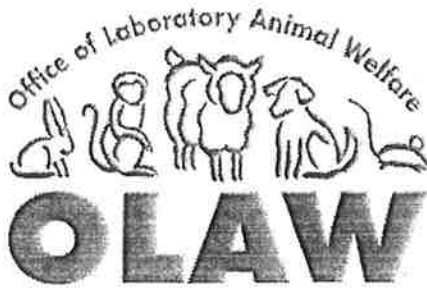
Did incident involve PHS funded activity? *NCI*
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened? *Unapproved resection of tumors. (Wound clips seen on OLAW site visit April 4, 2018) Also did not give required analgesics.*
 Species involved: *mice*
 Personnel involved: *PI*
 Dates and times: *4/4/18*
 Animal deaths: _____

Projected plan and schedule for correction/prevention (if known):
Probation (3-month), Protocol amended

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
 Case # _____



Division of Compliance Oversight

Record of Call for Case # A3518-1Q

Date & Time	Message	Initials
7/31/18 2:20	Spoke w/ Dr. Casebolt. IACUC met on 7/25/18. Final report will be sent soon.	<i>mgm</i>