



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

July 8, 2019

Re: Animal Welfare Assurance  
A3865-01 [OLAW Case V]

Dr. Joseph Incandela  
Vice Chancellor for Research  
University of California-Santa Barbara  
(b) (4) Cheadle Hall  
Santa Barbara, CA 93106-2050

Dear Dr. Incandela,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 21, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- Santa Barbara. According to the information provided, OLAW understands that a graduate student who had not been evaluated for proficiency for the specific procedure conducted a cranial surgery on a rat without supervision. The analgesic administration was not performed at the correct interval, the time of analgesia administration had not been recorded, and respiration rate and temperature were not monitored during surgery. The rat recovered normally from the procedure.

The corrective actions consisted of directing the Principal Investigator to revise the surgical training program to ensure that the surgeons are conducting procedures in accordance with the institutional rodent surgery guidelines. Investigators performing similar surgeries were notified by the Attending Veterinarian about the availability of oral analgesics. The rodent surgery guidelines will be revised to clarify the training requirements, competency evaluations, and record keeping requirements. Any individual found not to be proficient in conducting surgery may be removed from the protocol.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

## UC SANTA BARBARA

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Institutional Animal Care and Use Committee

Santa Barbara CA 93106-5062

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<https://www.research.ucsb.edu/compliance/animal-subjects/>

June 21, 2019

Animal Welfare Assurance A3865-01 (D16-00497)

Dr. Axel V. Wolff, Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institutes of Health

Rockledge One, Suite 360

6705 Rockledge Drive

Bethesda, MD 20892-7982

Dear Dr. Wolff,

In accordance with our Assurance and PHS Policy IV.F.3, I am writing to report an incident of protocol non-compliance involving the care and use of animals at the University of California, Santa Barbara. The UCSB IACUC is convinced that appropriate remediations were enacted to prevent recurrence of the incidents described below.

Summary of Investigation:

On Sunday April 21, 2019, an animal care technician noted that a rat recovering from surgery (craniotomy and cephalic implant) was lethargic and inactive, placed a pink Sick Card on the animal's cage and submitted a Clinical Call.

On Monday, April 22, 2019, the AV examined the rat and found it to be alert, active, recovering normally from surgery and not exhibiting signs of pain. The AV reviewed the surgery and post-operative recovery record and later contacted the PI and graduate student to ask several questions regarding missing or unclear documentation in these records, including: 1) Was the SpO2 really at 100% at each of the time points?, 2) Was the respiration rate being monitored during surgery?, 3) Was the body temperature being monitored and controlled during surgery?, 4) How much buprenorphine was administered, and when?, 5) How much bupivacaine was administered, and when?, 6) At what times on Sunday was the animal observed?, and 7) At what times on Sunday did the animal receive banamine? The graduate student responded that body temperature was not monitored, but a heating pad was used at all times; both bupivacaine and buprenorphine were administered preoperatively at 2 mg/kg and 0.05 mg/kg, respectively; and banamine was administered to the animal before and after surgery on April 20th, and again on April 21st and 22nd.

On April 25, 2019, the AV, IACUC Chair, PI and graduate student met to review these questions and issues.

On April 29, 2019, the IACUC Chair appointed a sub-Committee, comprised of himself and the AV, to investigate this incident further.

On May 7, 2019, the AV, IACUC Chair, and Coordinator met with the PI and the graduate students and postdoc. One of the graduate students stated that s/he performed the surgery (craniotomy and cephalic implant) on April 20, 2019 without trainer supervision, since s/he believed that s/he was approved to perform this surgery (craniotomy and cephalic implant) without direct supervision because s/he had previously completed a competency evaluation with the AV for a different surgical procedure (jugular vein catheterization and vascular access port implantation). The AV explained that researchers must complete a separate competency evaluation for each surgical procedure to be performed. The graduate student will continue to train on this surgical procedure under the direct supervision of the PI (trainer).

Additionally, the graduate student and PI misunderstood the treatment intervals for the postoperative banamine injections. The protocol states that "banamine or meloxicam and buprenorphine will be injected either before or during the surgical procedure, and then again (meloxicam or banamine) 1-2 times daily for at least 48 hrs after surgery". The graduate student confirmed that all of these analgesic treatments were administered and that s/he provided 4 injections of banamine to the rat within 48 hours of the surgery, but that the banamine treatments were not administered at 12h intervals. The times that these injections were administered is not recorded on the rat's postoperative record. Further, buprenorphine and bupivacaine treatments were also not documented on the rat's surgery record, nor was the rat's respiration rate monitored during surgery.

In an effort to prevent similar incidents in the future, the sub-Committee recommends that the PI revise his/her surgical training program to better familiarize the researchers conducting surgery on his/her protocols with the many details and expectations presented in the IACUC Guideline on Aseptic Rodent Surgery and Post-operative Care. The AV has notified all PIs performing similar survival surgical procedures on rats, and using banamine as an analgesic, about the availability of an alternative and more practical oral NSAID treatment (Carprofen MediGel). Additionally, the AV and IACUC will review and revise the rodent surgery guideline clarifying surgery training requirements, competency evaluations, and record keeping requirements. Finally, the IACUC wishes to emphasize that any person conducting surgeries for which they are not properly qualified and approved may be removed from the protocol.

This protocol is funded by two NIH grants (1R01EB022015-01A1 and 1R01AI45206-01). The UCSB Sponsored Projects Office (SPO) will work with the PI and NIH to ascertain if any grant money was used during this incident of protocol non-compliance. The final version of this report will be sent to OLAW and AAALAC.

If you have any additional questions or comments, please feel free to contact us. Thank you for your time.

Sincerely,

(b) (6)

Prof. Joseph Incandela

Institutional Official

Vice Chancellor for Research

(b) (4) Cheadle Hall

University of California, Santa Barbara

Santa Barbara, CA 93106-2050

incandela@research.ucsb.edu

Co: Dr. Stuart Feinstein, IACUC Chair  
Dr. Manuel Garcia, Campus Veterinarian  
IACUC Office

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, July 2, 2019 8:00 AM  
**To:** IACUC Office  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Incident Report for A3865-01

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

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

-----Original Message-----

From: IACUC Office <iacuc@lifesci.ucsb.edu>  
Sent: Monday, July 1, 2019 7:35 PM  
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
Cc: Joseph Incandela <incandela@research.ucsb.edu>; Stu Feinstein <stu.feinstein@lifesci.ucsb.edu>; Manny Garcia <manuel.garcia@ucsb.edu>; (b) (6)  
Subject: Incident Report for A3865-01

To Whom It May Concern:

Attached is a letter that details an incident of protocol noncompliance at the University of California, Santa Barbara (A3865-01).

The UCSB IACUC has investigated and reviewed the incident. This report includes the summary of the incident, as well as any Committee corrective actions.

Please let me know if there are any questions.

Sincerely,  
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(b) (6)