



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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 21, 2020

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

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 December 20, 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 two mice had undergone an approved surgery but it was not conducted as described in the protocol. Specifically, unapproved water restriction was used, a different water restriction log was used, post-operative analgesic was not given, and the surgical records were incomplete. One of the mice was dehydrated and had lost weight.

The corrective actions consisted of counseling the Principal Investigator and post-doctoral fellow involved to conduct procedures only as described in the approved protocol and to maintain adequate perioperative records. The protocol will be amended to describe water restriction, the Attending Veterinarian will check all surgical records to ensure completeness, and all animal users in the laboratory will be counseled on maintaining compliance with the protocol and institutional policies.

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/>

December 20, 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. Below is the full investigation report into IACUC protocol #4-19-950. Since the investigation and subsequent report have been completed in a timely manner, a preliminary report was not made and the full report is being sent to OLAW. The IACUC is convinced that appropriate remediations were enacted to prevent recurrence of the incidents described below.

## Summary of Investigation:

On November 12, 2019, the Attending Veterinarian (AV) contacted a Principal Investigator (PI) and a postdoc in her/his lab regarding two mice that each underwent a head plate implantation surgery on November 7, 2019. The AV

determined that one of the mice that underwent surgery was dehydrated and had lost 20% of its pre-surgical body weight. The AV also expressed multiple concerns regarding the well-being of the animals when he reviewed their corresponding records. 1) The mice were being water-restricted at the time they underwent surgery, which was not approved in the protocol, 2) the log sheet being used to track the water restriction regimen for the mice was not the one that the postdoc had agreed to use and did not capture data on all of the required monitoring parameters, 3) the postoperative analgesic (Carprofen) was not administered to the mice on any of the days following surgery, and 4) the Rodent Survival Surgery and Postoperative Care Log should have been filled out more thoroughly. Upon being notified of the AV's concerns, the IACUC Chair formed a sub-Committee to investigate the incident further.

On November 14, 2019, the IACUC Chair, Coordinator, and AV met with the PI and the postdoc that conducted the surgeries. During this meeting, each of the AV's concerns were discussed. When asked why the mice were being water restricted prior to undergoing surgery, the PI responded that this had been his/her lab's intention when writing the protocol, but this provision may not have been as well defined as s/he had intended. The PI confirmed that s/he would be submitting a protocol modification to clarify this point.

When asked about why the agreed upon water restriction log was not used, the postdoc responded that s/he found the format to be "inefficient" in that it requires each animal to have its own separate log sheet. The approved protocol states that the lab will monitor and maintain detailed records of the "body weight (bi-weekly), water consumption (daily), and health status (daily)" for all mice undergoing water restriction to ensure they do not lose more than 20% body weight or otherwise appear unhealthy. The AV had previously recommended to the postdoc that they should use a log developed by another lab on campus that employs nearly identical water restriction requirements, which would document all of the required monitoring parameters. The postdoc stated that instead of using this log, s/he has kept an electronic record for all the mice on water restriction in her/his "lab notebook" stored on Google Drive. This electronic record was subsequently shared with the AV

and found to not contain any information on the health status of the animals. The sub-Committee reminded the PI and postdoc that physical copies of records should be kept where the animals are housed so that they are accessible to the AV and ARC staff at all times.

When asked why the animals did not receive analgesia for three days postoperatively, as described in the protocol, the postdoc indicated that postoperative analgesics had been generally administered to animals only "as needed" (i.e., based on appearance) at their previous institution from which they had recently left. The Chair emphasized that while this may have been the standard at the PI and postdoc's previous institution, all researchers at UCSB are expected and required to perform their animal experiments and procedures exactly as described in their UCSB approved IACUC protocol. The protocol did not state that animals would receive postoperative analgesia as needed, rather, that they would receive postoperative analgesia. The PI mentioned that s/he is looking into the possibility of administering postoperative analgesics to animals via an oral route (e.g., medicate gel).

With regard to how the Rodent Survival Surgery and Postoperative Care Log had been filled out by the postdoc, the following issues were noted. 1) The Animal ID#s on the Log did not match the Cage IDs on the animal's cage cards, 2) the duration for which Carprofen should be administered postoperatively was not listed, and 3) the sections where the daily postoperative health checks and analgesia administrations are documented were not dated or initialed. The Chair reminded the PI and postdoc of the importance and necessity of keeping complete records to document the appropriate performance of anesthesia, surgery, and postoperative care according to the approved protocol.

On December 13, 2019, the IACUC Chair presented this investigation report to the IACUC at a convened meeting. The Committee confirmed that the reminders given to the PI and postdoc by the IACUC Chair during their meeting had sufficiently communicated the IACUC's expectations regarding surgical and postoperative procedures. The AV confirmed that the required monitoring parameters for the

water-restricted mice are now being recorded in the postdoc's online "lab notebook". Additionally, the AV has recently begun regular checks of surgical records for animals housed in the ARC to ensure that they are properly completed and contain the required information. The PI has yet to submit a protocol modification to include the provision of performing surgery on mice that are undergoing water-restriction. This protocol is funded by NIH grant 7R01EY024294-05. The Committee voted that this incident is reportable to both OLAW and AAALAC. Finally, the Chair, AV and Coordinator will be setting up a meeting in January with all animal users in the lab early to reinforce all of the points discussed at the November 14th meeting to ensure that the necessary information has been communicated and to emphasize that complete compliance with all aspects of the protocol and the UCSB Animal Use and Care Program must be maintained.

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

Cc: 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:** Friday, January 17, 2020 1:08 PM  
**To:** IACUC Office  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Incident Report for A3865-01

Thanks 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:** Friday, January 17, 2020 12:26 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Joseph Incandela <incandela@research.ucsb.edu>; Stu Feinstein <feinstei@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/D16-00497). 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,  
(b) (6)

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(b) (6)