

Subject: OLAW Case A3865-T

From: "[REDACTED] (NIH/OD) [E]" [REDACTED]

Date: 11/27/2018, 8:29 AM

To: "vicechancellor@research.ucsb.edu" <vicechancellor@research.ucsb.edu>

CC: "iacuc@lifesci.ucsb.edu" <iacuc@lifesci.ucsb.edu>

Dear Dr. Incandela,

Attached please find [REDACTED] final response to OLAW Case A3865-T.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,

[REDACTED]

[REDACTED]

*Office of Laboratory Animal Welfare
National Institutes of Health*

[REDACTED]

— Attachments: —

3241_001.pdf

56.6 KB



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

November 27, 2018

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

Dr. Joseph Incandela
Vice Chancellor for Research
University of California-Santa Barbara
3227 Cheadle Hall
Santa Barbara, CA 93106-2050

Dear Dr. Incandela,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 1, 2018 letter reporting the suspension of animal activities on four protocols at the University of California- Santa Barbara. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that the Principal Investigator would not be on campus for an extended period and could not carry out the activities on the approved protocols or oversee the animals. The animals were transferred to the Attending Veterinarian's holding protocol. The protocols were not federally funded.

Based on its assessment of this explanation, OLAW understands the IACUC's reasoning for enacting the suspensions but notes that it is also acceptable to transfer animals on active protocols to holding protocols without resorting to suspension. Reasons for such transfers include absence of the investigator, lack of a protocol, and protocol expirations. Suspensions are considered to be very serious actions usually taken in response to unresolved noncompliance. Suspensions of federally supported activities must also be reported to the funding component and animal activities cannot be charged to the grant.

We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Office of Laboratory Animal Welfare

cc: IACUC Chair

Subject: RE: Incident Report for A3865-01

From: "OLAW Division of Compliance Oversight (NIH/OD)" [REDACTED]

Date: 6/5/2019, 4:25 AM

To: IACUC Office <iacuc@lifesci.ucsb.edu>, "OLAW Division of Compliance Oversight (NIH/OD)" [REDACTED]

CC: Joseph Incandela <incandela@research.ucsb.edu>, Manny Garcia <manuel.garcia@ucsb.edu>, Stu Feinstein <stu.feinstein@lifesci.ucsb.edu>, [REDACTED]

Thank you for providing this report. Please have the Institutional Official, as the legal representative, sign the report or provide a cover letter, or otherwise acknowledge agreement with the IACUC's findings and corrective and preventive measures. Thank you again.

Sincerely, [REDACTED]

[REDACTED]
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.

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

From: IACUC Office [<mailto:iacuc@lifesci.ucsb.edu>]

Sent: Tuesday, June 04, 2019 6:55 PM

To: OLAW Division of Compliance Oversight (NIH/OD) [REDACTED]

Cc: Joseph Incandela <incandela@research.ucsb.edu>; Manny Garcia <manuel.garcia@ucsb.edu>;

Stu Feinstein <stu.feinstein@lifesci.ucsb.edu>; [REDACTED]

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,

[REDACTED]

--

[REDACTED] UCSB
[REDACTED]
Santa Barbara, CA 93106-5062
(805)893-[REDACTED] (office)
(805)893-2005 (FAX)

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

UCSB IACUC INVESTIGATION CHECKLIST

Summary of Investigation:

On April 3, 2019, the IACUC Office received a forwarded message from the PI regarding his/her mice in the vivarium. The [REDACTED] had emailed the PI to notify her/him that the mice on her/his protocol were now one month past the experimental endpoint identified in their IACUC protocol. While the ARC staff had been hired by the PI to administer an experimental compound to the mice, the experimental treatment schedule was set by the PI and the ARC staff was responsible only for administering the experimental compound at bi-weekly (twice per week) intervals. The experimental compound was prepared and delivered by the lab to the ARC before each treatment (i.e., bi-weekly). The PI notified the IACUC Office that they would be euthanizing all of the mice in their colony within twelve days. The IACUC Chair subsequently asked to meet with the PI to regarding the change in the experimental endpoint for the mice.

The mice being used on the protocol were a transgenic strain, rTg4510, which is a commonly used model for studying the formation of neurofibrillary tangles associated with Alzheimer's disease and related neurodegenerative tauopathies such as frontotemporal dementia. These mice exhibit experimentally useful neurological phenotypes (impaired spatial learning and memory) and a potentially distressful phenotype in later stages (>6.5 months of age) in the form of progressive motor function abnormalities (amyotrophy and motor disturbance). From the protocol: "pathological lesions (mature tangles) are observed beginning at 2.5 months of age, and memory dysfunction is observed at 4.5 months". The endpoint outlined in the protocol states that an experimental compound (Cinnamaldehyde) will be tested for its ability to "alleviate/attenuate both tau tangles and behavioral pathology" at 6-6.5 months of age, "since this is the time at which memory dysfunction has been reported for this mouse model". The mice were to be euthanized for tissue collection at 6.5 months of age.

The IACUC Chair appointed a sub-Committee, comprised of himself and the Attending Veterinarian (AV), to investigate this potential incident of protocol non-compliance. On April 15, 2019, the [REDACTED], Chair and AV met with the PI and another faculty member who had been enlisted to perform the euthanasia and tissue collection procedures. The PI confirmed at the meeting that all of the mice in this experiment (approximately 80 animals) had been euthanized. When asked why these mice were not euthanized according to the experimental endpoint described in the protocol, the PI stated that s/he was not aware of the birthdates of the mice (i.e., s/he had not been tracking their ages). The PI explained that the mice needed to undergo behavioral testing prior to the tissue collection, however, the faculty member who was to perform the behavioral testing procedures for the PI had not started the testing early enough to complete it prior to the experimental endpoint. The PI confirmed that s/he was not planning on using any more animals under this protocol, unless requested by journal article reviewers.

After meeting with the PI, the [REDACTED], Chair and AV met with the [REDACTED]. S/he confirmed that the ARC had been administering the experimental compound to the mice according to the treatment plan set by the PI. While the [REDACTED] and the AV confirmed that no mice had been exhibiting symptoms of the potentially distressful phenotype, the [REDACTED] did mention that the mice were not looking as bright and active as they had been in previous months.

During the April 19, 2019 convened IACUC meeting, the IACUC Chair summarized the situation for the Committee and led a discussion of whether or not this incident was reportable to OLAW. This project is funded by an NIH grant (). Following a discussion, the Committee voted that this incident should be reported to OLAW according to the Guidance of Prompt Reporting outlined in OLAW NOT-OD-05-034. A preliminary report via phone call was made to OLAW's Division of Compliance Oversight by the IACUC Chair on May 3, 2019.

During the May 17, 2019 convened IACUC meeting, the IACUC Chair summarized the discussion with OLAW's Division of Compliance Oversight, noting that they had specifically asked about remediation to prevent similar incidents in the future. The IACUC will require a signed statement from the PI and all personnel listed on the training roster attesting that they have read the protocol and will read all subsequent modifications. If the PI submits another IACUC protocol application in the future, s/he and all personnel on that protocol will be required to sign a similar attestation. The IACUC Chair also stated that he is planning on creating an assurance statement, based on the protocol assurance statement that PI's are already required to sign, that must be signed by all researchers working with animals to affirm that each of them has read and understands the procedures in the protocol and all applicable modifications. The final version of this investigation report will be sent to OLAW and AAALAC.

PROTOCOL (PI being investigated)

Principal Investigator: [REDACTED]	Phone: [REDACTED]
Co-PI: [REDACTED]	Phone: [REDACTED]
Complete IACUC #: [REDACTED]	IACUC Title: [REDACTED] [REDACTED]
Species/Strain: Tg4510 Mice	Current housing location:

EVALUATION BY IACUC

- ☐ No further investigation warranted – Date: _____
- ☒ Proceed with investigation
- ☒ Notify Institutional Official
- ☒ Sub-Committee Appointed: 1. Stu Feinstein
2. Manny Garcia
- ☒ Report of Investigation (by Sub-Committee to the IACUC) submitted
- ☒ Convened IACUC meeting review - Date: May 17, 2019

☒ Final IACUC action – Date: May 17, 2019

☒ Notifications required (list): IO, PI, Co-PI, AV, IACUC Chair, [REDACTED],
OLAW, AAALAC

☒ Notifications sent - Date: June 4, 2019

Subject: Incident Report for A3865-01

From: IACUC Office <iacuc@lifesci.ucsb.edu>

Date: 6/24/2019, 3:00 PM

To: [REDACTED]

CC: Joseph Incandela <incandela@research.ucsb.edu>, Manny Garcia <manuel.garcia@ucsb.edu>, Stu Feinstein <stu.feinstein@lifesci.ucsb.edu>, [REDACTED]

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,

[REDACTED]

--

[REDACTED] UCSB
[REDACTED]

Santa Barbara, CA 93106-5062

(805)893-[REDACTED] (office)

(805)893-2005 (FAX)

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

— Attachments: —

[REDACTED]_Report_to_OLAW_6-2019.pdf

90.9 KB

UC SANTA BARBARA

Institutional Animal Care and Use Committee

Santa Barbara CA 93106-5062

Tel: (805) 893-██████

Fax: (805) 893-2005

Email: iacuc@lifesci.ucsb.edu

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

June 20, 2019

Animal Welfare Assurance A3865-01 (D16-00497)

████████████████████
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

████████████████████
████████████████████
████████████████████

Dear ██████████

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 the incident preliminarily reported to you via a phone call from our IACUC Chair on May 3, 2019. The UCSB IACUC is convinced that appropriate remediations were enacted to prevent recurrence of the incidents described below.

Summary of Investigation:

On April 3, 2019, the IACUC Office received a forwarded message from the PI regarding his/her mice in the vivarium. The ██████████ had emailed the PI to notify her/him that the mice on her/his protocol were now one month past the experimental endpoint identified in their IACUC protocol. While the ARC staff had

been hired by the PI to administer an experimental compound to the mice, the experimental treatment schedule was set by the PI and the ARC staff was responsible only for administering the experimental compound at bi-weekly (twice per week) intervals. The experimental compound was prepared and delivered by the lab to the ARC before each treatment (i.e., bi-weekly). The PI notified the IACUC Office that they would be euthanizing all of the mice in their colony within twelve days. The IACUC Chair subsequently asked to meet with the PI to regarding the change in the experimental endpoint for the mice.

The mice being used on the protocol were a transgenic strain, rTg4510, which is a commonly used model for studying the formation of neurofibrillary tangles associated with Alzheimer's disease and related neurodegenerative tauopathies such as frontotemporal dementia. These mice exhibit experimentally useful neurological phenotypes (impaired spatial learning and memory) and a potentially distressful phenotype in later stages (>6.5 months of age) in the form of progressive motor function abnormalities (amyotrophy and motor disturbance). From the protocol: [REDACTED]

[REDACTED]. The endpoint outlined in the protocol states that an experimental compound (Cinnamaldehyde) will be tested for its ability to [REDACTED]

[REDACTED] at 6-6.5 months of age, [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED] The mice were to be euthanized for tissue collection at 6.5 months of age.

The IACUC Chair appointed a sub-Committee, comprised of himself and the Attending Veterinarian (AV), to investigate this potential incident of protocol non-compliance. On April 15, 2019, the [REDACTED], Chair and AV met with the PI and another faculty member who had been enlisted to perform the euthanasia and tissue collection procedures. The PI confirmed at the meeting that all of the mice in this experiment (approximately 80 animals) had been euthanized. When asked why these mice were not euthanized according to the experimental endpoint described in the protocol, the PI admitted that it was due to (his own) human error. One of the collaborating investigators was not yet ready to carry out their studies as

previously planned, and consequently it was necessary to hold on to the animals longer than expected. Amidst this procedural adjustment, the PI admitted that he inadvertently overlooked the date of euthanization (March 7, 2019) stated in the most recent modification to the animal protocol. The PI confirmed that s/he was not planning on using any more animals under this protocol, unless requested by journal article reviewers.

After meeting with the PI, [REDACTED], Chair and AV met with the [REDACTED]. S/he confirmed that the ARC had been administering the experimental compound to the mice according to the treatment plan set by the PI. While the [REDACTED] and the AV confirmed that no mice had been exhibiting symptoms of the potentially distressful phenotype, the [REDACTED] did mention that the mice were not looking as bright and active as they had been in previous months.

During the April 19, 2019 convened IACUC meeting, the IACUC Chair summarized the situation for the Committee and led a discussion of whether or not this incident was reportable to OLAW. This project is funded by an NIH grant ([REDACTED]). Following a discussion, the Committee voted that this incident should be reported to OLAW according to the Guidance of Prompt Reporting outlined in OLAW NOT-OD-05-034. A preliminary report via phone call was made to OLAW's Division of Compliance Oversight by the IACUC Chair on May 3, 2019.

During the May 17, 2019 convened IACUC meeting, the IACUC Chair summarized the discussion with OLAW's Division of Compliance Oversight, noting that they had specifically asked about remediation to prevent similar incidents in the future. The IACUC will require a signed statement from the PI and all personnel listed on the training roster attesting that they have read the protocol and will read all subsequent modifications. If the PI submits another IACUC protocol application in the future, s/he and all personnel on that protocol will be required to sign a similar attestation. The IACUC Chair also stated that he is planning on creating an assurance statement, based on the protocol assurance statement that PI's are already required to sign, that must be signed by all researchers working with animals to affirm that each of them has read and understands the procedures in the

protocol and all applicable modifications. The final version of this investigation report will be sent to OLAW and AAALAC.

This protocol is funded by an NIH grant ([REDACTED]). 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.

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

Sincerely,



Prof. Joseph Incandela
Institutional Official
Vice Chancellor for Research
3227 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

UC SANTA BARBARA

Institutional Animal Care and Use Committee

Santa Barbara CA 93106-5062

Tel: (805) 893-██████

Fax: (805) 893-2005

Email: iacuc@lifesci.ucsb.edu

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

June 21, 2019

Animal Welfare Assurance A3865-01 (D16-00497)

████████████████████
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
████████████████████
████████████████████
████████████████████

Dear ██████████,

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 [REDACTED] 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 [REDACTED]

[REDACTED]. 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 ([REDACTED] and [REDACTED]). 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,

A handwritten signature in black ink, appearing to read 'J. Incandela', with a long horizontal flourish extending to the right.

Prof. Joseph Incandela

Institutional Official

Vice Chancellor for Research

3227 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

Subject: RE: FW: Incident Report for A3865-01

From: "OLAW Division of Compliance Oversight (NIH/OD)" [REDACTED]

Date: 7/5/2019, 4:01 AM

To: IACUC Office <iacuc@lifesci.ucsb.edu>

CC: "OLAW Division of Compliance Oversight (NIH/OD)" [REDACTED]

Thanks for sending it again. I will send the response shortly.
[REDACTED]

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

From: IACUC Office <iacuc@lifesci.ucsb.edu>

Sent: Wednesday, July 3, 2019 6:48 PM

To: OLAW Division of Compliance Oversight (NIH/OD) [REDACTED]

Subject: Re: FW: Incident Report for A3865-01

Hi [REDACTED],

I actually did resubmit that report to OLAW with our IO's signature on June 24th. I've attached the .pdf to this email. Please let me know if you have any other questions.

Thanks,
[REDACTED]

On 7/2/2019 10:45 AM, OLAW Division of Compliance Oversight (NIH/OD) wrote:

Hello [REDACTED], in reviewing this case I noted that a previous case you had submitted never came with the final signed copy from the IO. It was sent June 4 and involved 80 mice on an Alzheimer study which were not euthanized at the timepoint described in the protocol. Please have Dr. Incandela sign the report and forward to OLAW. Thanks.
[REDACTED]

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

From: OLAW Division of Compliance Oversight (NIH/OD)
[REDACTED]

Sent: Tuesday, July 2, 2019 8:00 AM

To: IACUC Office <iacuc@lifesci.ucsb.edu>

Cc: OLAW Division of Compliance Oversight (NIH/OD)
[REDACTED]

Subject: RE: Incident Report for A3865-01

Thank you for this report, [REDACTED]. We will send a response soon.
[REDACTED]

-----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)
[REDACTED]

Cc: Joseph Incandela <incandela@research.ucsb.edu>; Stu Feinstein
<stu.feinstein@lifesci.ucsb.edu>; Manny Garcia
<manuel.garcia@ucsb.edu>; [REDACTED]

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,

[REDACTED]

--

[REDACTED]

UCSB

Santa Barbara, CA 93106-5062

(805)893-[REDACTED] (office)

(805)893-2005 (FAX)

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

--

[REDACTED]

, UCSB

Santa Barbara, CA 93106-5062

(805)893-[REDACTED] (office)

(805)893-2005 (FAX)

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

Subject: Re: OLAW Cases A3865-U and V

From: Joseph Incandela <incandela@research.ucsb.edu>

Date: 7/8/2019, 12:19 PM

To: "[REDACTED] (NIH/OD) [E]" [REDACTED]

CC: "iacuc@lifesci.ucsb.edu" <iacuc@lifesci.ucsb.edu>, "stu.feinstein@lifesci.ucsb.edu" <stu.feinstein@lifesci.ucsb.edu>

Dear [REDACTED],

Please thank [REDACTED] for his prompt attention and response. We are glad to read that OLAW concurs with the actions that we have taken.

Best Regards,

Joe Incandela

On 7/8/19 7:34 PM, Ward, Joan (NIH/OD) [E] wrote:

Dear Dr. Incandela,

Attached please find [REDACTED] final response to OLAW Cases A3865-U and V.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,

[REDACTED]

[REDACTED]
Office of Laboratory Animal Welfare
National Institutes of Health

[REDACTED]

--

Joe Incandela

Vice Chancellor for Research

Office of Research

Office: (805) 893-8270

UC SANTA BARBARA

University of California, Santa Barbara

Santa Barbara, California 93106

(805) 893-8370



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 U]

Dr. Joseph Incandela
Vice Chancellor for Research
University of California-Santa Barbara
3227 Cheadle Hall
Santa Barbara, CA 93106-2050

Dear Dr. Incandela,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 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, following up on an initial telephone report on May 3, 2019 and an interim report on June 4, 2019 . According to the information provided, OLAW understands that 80 mice on an Alzheimer disease study were not euthanized at the timepoint described in the protocol, but rather one month later. Although the mice were not as active as they had been previously, they were not noted to be in pain or distress.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring certification by all Principal Investigators (PI) and staff that they have read the protocol and any amendments and understand the approved procedures. The PI involved stated that no additional animal work will be conducted on this 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 IACUC to comply with the PHS Policy.

Sincerely,

Office of Laboratory Animal Welfare

cc: IACUC Chair



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
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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
3227 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,

Office of Laboratory Animal Welfare

cc: IACUC Chair