



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 1, 2022

Re: Animal Welfare Assurance
A3400-01 [OLAW Case 4N]

Mr. Brian Smith
Associate Vice Chancellor for
Research Infrastructure and Operations
University of California, San Francisco
3333 California Street, (b) (4)
San Francisco, CA 94118

Dear Mr. Smith,

The Office of Laboratory Animal Welfare (OLAW) acknowledges your January 7, 2022 letter, received in our office on January 21, 2022, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California – San Francisco. Your letter supplemented the information contained in the initial telephone report to this Office on June 11, 2021. According to the information provided, OLAW understands that a lab did not administer all post-operative analgesics required by the protocol to mice in March and May of 2021. There were no reports of adverse effects in these animals. This was a PHS-funded study.

Corrective and preventive measures included:

1. a protocol modification to update the post-operative analgesia plan.
2. the lab completed Post-Approval Survival Surgical Review (PASSR) training.
3. each surgeon submitted surgical records for immediate review by IACUC staff, and subsequently submitted surgical records for 3 months.
4. all lab members reviewed and confirmed understanding of the relevant protocol.

The laboratory is currently in compliance with UCSF and PHS standards.

OLAW appreciates the prompt consideration of this matter by the University of California – San Francisco, 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 correct the deficiency and prevent recurrence. OLAW concurs that the issue warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse

S

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

Digitally signed by Brent C.
Morse -S
Date: 2022.02.01 09:18:05
-05'00'

cc: IACUC Chair



University of California
San Francisco

Brian E Smith, JD, MBA
Chief Ethics and Compliance Officer
Senior Associate Vice Chancellor -
Research

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January 7, 2022

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Animal Welfare Assurance: #A3400-01 - Final Follow-up Reporting

Dear Dr. Morse,

This letter serves as final follow-up to our preliminary non-compliance report to OLAW on June 11, 2021.

A review of the lab's surgical records for March and May 2021 showed that lab did not administer all post-operative analgesics required by the protocol to mice for an NIH-funded study. At the time of this finding, the post-surgical period had passed and there were no reports of adverse effects in these animals.

Follow-up and Corrective Action:

1. The PI submitted a protocol modification to update the post-operative analgesia plan that was subsequently approved by the IACUC, including LARC veterinary review.
2. The lab completed Post-Approval Survival Surgical Review (PASSR) training with IACUP Staff.
3. Each surgeon submitted surgical records for immediate review by IACUP staff, and subsequently submitted surgical records for 3 months.
4. All lab members reviewed and confirmed understanding of the relevant protocol.

Completion:

As of the date of this letter, corrective actions #1-4 above are complete. The laboratory is currently in compliance with UCSF and PHS standards. I believe the steps taken will help ensure future compliance and prevent reoccurrence. If you have any additional questions, please do not hesitate to contact me or the IACUP Director.

Sincerely,

DocuSigned by:

(b) (6)

Brian E Smith, JD, MBA
Chief Ethics and Compliance Officer
Senior Associate Vice Chancellor - Research
Institutional Official

cc: Attending Veterinarian and LARC Director
IACUC Chair



Morse, Brent (NIH/OD) [E]

From: (b) (6)
Sent: Wednesday, November 10, 2021 3:48 PM
To: Morse, Brent (NIH/OD) [E]
Subject: RE: June 2021 preliminary report?

Follow Up Flag: Follow up
Flag Status: Flagged

Good afternoon Brent,

My apologies for our oversight. She recently provided me drafts for a few items to review, including this one. We will obtain IO signature on the final report and submit to you by the end of next week.

Best,

(b) (6)

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Wednesday, November 10, 2021 6:31 AM
To: (b) (6)
Subject: June 2021 preliminary report?
Importance: High

This Message Is From an External Sender

This message came from outside your organization.

Hello (b) (6)

Sorry to bother you, but I don't have an email address for (b) (6). She made a telephone preliminary report on June 11 regarding a PHS-funded mouse study where mice received incomplete administration of analgesia after intracranial surgery. We haven't received further information or a final report. Would you please send an update or the final report? Thank you.

Sincerely, Brent

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, January 24, 2022 8:42 AM
To: (b) (6)
Cc: (b) (6)
Subject: RE: Final Reports for D16-00253 (A3400-01)

Thank you for providing these. We'll send official responses soon.

Best regards, Brent Morse

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

From: (b) (6)
Sent: Friday, January 21, 2022 8:07 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] Final Reports for D16-00253 (A3400-01)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Morse,

Please find attached two final reports for previously reported non-compliances. If you have any questions, feel free to call or email me.

Best,

(b) (6)



Initial Report of Noncompliance

By: BCM

Date: 6/11/2021

Time: 2:05

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: UCSF

Assurance number: A3400

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened?

Incomplete analgesia administered after intracranial surgery.

Species involved: mus musculus

Personnel involved: ?

Dates and times: ?

Animal deaths:

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

IACUC investigating

Projected submission to OLAW of final report from Institutional Official:

< 60 days.

OFFICE USE ONLY

Case #