



Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD 20737

December 18, 2019

University Of California-San Diego
IACUC Office, Mail Code 0071
9500 Gilman Drive
La Jolla, CA 92093

Registration: 93-R-0437
Customer ID: 9196

Dear (b) (6), (b) (7)(C)

Your September 2019 appeal of citations on the USDA inspection report dated August 21, 2019 was thoroughly reviewed by an Animal Care appeal panel consisting of two Supervisory Animal Care Specialists, an Assistant Director, and myself. The appeal is addressed below:

2.31 (c) (7) will be changed to 2.32 (a).

- As you stated in your appeal letter, this incident was not related to the IACUC failing to review and approve changes to the care and use of animals since no changes to the protocol were made. This non-compliance is more appropriately documented under section 2.32 (a). The facility is responsible for ensuring their personnel are qualified to perform their duties, including such duties as calculating and administering correct dosages of drugs or compounds to animals.
- We appreciate your efforts to reevaluate and adjust the laboratory's dosing procedures to help prevent recurrence.

It is my understanding that the inspectors discussed the Animal Care Incentives program with you. For more information, you may visit the guidance documents section, including "Incentive for Animal Welfare Act Compliance", at the Animal Care website:

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_publications/ct_publications_and_guidance_documents

You should receive a copy of the amended inspection report within two weeks.

All decisions made by the appeal panel are final and represent Animal Care's final determination for this appeal.

Sincerely,

DANA COLE

Digitally signed by DANA COLE
Date: 2019.12.19 09:37:02
-07'00'

Dana Cole, DVM
Acting Director, Animal Welfare Operations
USDA, APHIS, Animal Care

USDA Animal Care. Ensuring humane treatment. Serving people. Doing right.

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OFFICE OF RESEARCH AFFAIRS
TEL: (858) 534-3526
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9500 GILMAN DRIVE # 0043
LA JOLLA, CALIFORNIA 92093-0043
EMAIL: VCRESEARCH@UCSD.EDU
URL: RESEARCH.UCSD.EDU

September 12, 2019

Robert M Gibbens, DVM
Director, Animal Care Western Region
United States Department of Agriculture
2150 Centre Ave., Building B, Mailstop #3W11
Fort Collins, CO 80526-8117

SUBJECT: Appeal to the University of California San Diego Inspection Report Dated August 26, 2019 – Citation 2.31(c)(7)

Dear Dr. Gibbens,

The University of California San Diego (UC San Diego) seeks to appeal the following citation listed in the August 26, 2019, United States Department of Agriculture (USDA) inspection report:

**"2.31(c)(7) CRITICAL
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

In October 2018, due to a miscalculation and dosing error, six rabbits were injected with a higher dose of barium chloride than was approved in the protocol. The following day, two rabbits had died and the remaining four were reported to the Animal Care Program and humanely euthanized.

The IACUC is responsible for reviewing and approving proposed significant changes regarding the care and use of animals. Unapproved modifications may be detrimental to the health and welfare of animals.

Primary investigators shall adhere to approved protocols and procedures. The IACUC shall review and approve any modifications to approved protocols.

Corrected prior to inspection."

We would like to affirm that per the Animal Welfare Regulations, the UC San Diego Institutional Animal Care and Use Committee (IACUC) does indeed always "Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities" (9 CFR AWR 2.31(c)(7)). In this unfortunate incident, the investigator never intended to amend nor deviate from his approved protocol. Rather, what occurred was a dosing calculation error that resulted in an adverse outcome. The laboratory's internal practices related to the dosing procedure were reevaluated and adjusted to prevent recurrence.

Given our belief that the IACUC was not remiss in performing its responsibilities required by the Animal Welfare Regulations, we request your consideration of our appeal to remove this citation from the August 26, 2019, inspection report.

If you have any questions, please contact me at (b) (6), (b) (7)(C) or (b) (6), (b) (7)(C)@ucsd.edu.

Sincerely,

(b) (6), (b) (7)(C)

cc:

(b) (6), (b) (7)(C)



Inspection Report

University Of California-San Diego
Iacuc Office, Mail Code 0071
9500 Gilman Drive
La Jolla, CA 92093

Customer ID: 9196

Certificate: 93-R-0437

Site: 001

THE UNIVERSITY OF CALIFORNIA, SAN DIEGO

Type: FOCUSED INSPECTION

Date: 21-AUG-2019

2.32(a) CRITICAL

PERSONNEL QUALIFICATIONS.

In October 2018, due to a miscalculation and dosing error, six rabbits were injected with a higher dose of barium chloride than was approved in the protocol. The following day, two rabbits had died and the remaining four were reported to the Animal Care Program and humanely euthanized.

The research facility is responsible for ensuring that all personnel involved in animal care, treatment, and use are qualified to perform their duties. Errors in medication administration may be detrimental to the health and welfare of animals.

The research facility shall ensure that all personnel are qualified to perform their duties.

Corrected prior to inspection.

Additional Inspectors

Gonzalez Elba, Veterinary Medical Officer

Schnell Michael, Veterinary Medical Officer

Prepared By:

AMANDA WHITE

Digitally signed by AMANDA WHITE

Date: 2019.12.31 13:32:38 -08'00'

WHITE AMANDA, D V M

USDA, APHIS, Animal Care

Date:

31-DEC-2019

Title: VETERINARY MEDICAL OFFICER 6131

Received By: 003_000132

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/24/2020

Date:

(b) (6), (b) (7)(C)



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
9196	93-R-0437	001	THE UNIVERSITY OF CALIFORNIA, SAN DIEGO	21-AUG-19

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

(b) (6), (b) (7)(C)

To: [White, Amanda M - APHIS](#)
Subject: Re: Amended Inspection report attached - Please respond
Date: Tuesday, December 31, 2019 6:05:42 PM

Hello Amanda:

I have just reviewed the appeals response as well as the amended inspection report you sent.
Thanks so much for sending and all of your efforts.

Hope you are having a great holiday season—also wishing you the best in 2020.

Hope to see you soon.

Many thanks,

(b) (6), (b) (7)(C)

On Dec 31, 2019, at 1:48 PM, White, Amanda M - APHIS
<amanda.m.white@usda.gov> wrote:

(b) (6), (b) (7)(C)

I hope you've had an opportunity to review the response from our appeals team. I've attached a copy of the response letter here, for your reference.

I've also attached the amended inspection report
(IR_9196_001_UCSD_21AUG2019_Amended).

Please open the file, read it, *and reply to this email that you have received it.*

Your email reply will serve as your received signature for this report.

Thanks so much for your time, and please let me know if you have questions or concerns.

Wishing you all the best for 2020! I look forward to working with you again in the future.

Thank you,

Amanda

Enclosures (2):

AppealResponse_9196_001_UCSD_18DEC2019

IR_9196_001_UCSD_21AUG2019_Amended

Amanda M. White, DVM, MPVM, DACVPM
Veterinary Medical Officer
Animal Welfare Operations (California)

USDA-APHIS, Animal Care

Cell: 442-400-9212

Email: Amanda.M.White@usda.gov

 [Click here to subscribe to the Animal Care Stakeholder Registry](#)

From: White, Amanda M - APHIS

Sent: Monday, August 26, 2019 9:15 AM

(b) (6), (b) (7)(C) [\[REDACTED\]@ucsd.edu](mailto:[REDACTED]@ucsd.edu)

Subject: Inspection report attached - Please respond

(b) (6), (b) (7)(C)

It was a pleasure to meet you and your colleagues. Attached is the inspection report generated from your recent inspection.

Please open the file, read it, and reply to this email that you have received it. Your email reply will serve as your received signature for this report.

Thanks so much for your time, and please let me know if you have questions or concerns.

Amanda

Enclosures (1):

IR_9196_001_UCSD_21AUG2019

Amanda M. White, DVM, MPVM, DACVPM

Veterinary Medical Officer

Animal Welfare Operations (California)

USDA-APHIS, Animal Care

Cell: 442-400-9212

Email: Amanda.M.White@usda.gov

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<IR_9196_001_UCSD_21AUG2019_Amended.pdf><AppealResponse_9196_00

1_UCSD_18DEC2019.pdf>