

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

January 15, 2019

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PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telcohone: (301) 496-7163 Eassimile: (301) 402-7065

Re: Animal Welfare Assurance A3033-01 [OLAW Case 2A]

Dr. Sandra A. Brown Vice Chancellor for Research Affairs University of California-San Diego 9500 Gilman Drive, LaJolla, CA 92093-0043

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 11, 2019 response to my December 26, 2018 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- San Diego. According to the information provided, OLAW understands that to prevent future miscalculation of drug dosages, the laboratory will now obtain concentrated liquid solution for dilution. Another technician or the Principal Investigator will verify the dilution and only one rabbit will be initially injected and observed for one day before the other animals are injected.

Based on its assessment of this explanation, OLAW has a better understanding of the measures taken to prevent recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. We assume the protocol was amended to reflect these changes. Thank you keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair Robert Gibbens, D.V.M., USDA-APHIS-AC

(b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)	
Sent:	Monday, January 14, 2019 3:43 PM	
То:	IACUC; OLAW Division of Compliance Oversight (NIH/OD)	
Cc:	Brown, Sandra; Richter, Philip; (b) (6) McMahill, Angela; Anderson-Vicino,	
	Kristen	
Subject:	RE: Response from University of California, San Diego	
Follow Up Flag:	Follow up	
Flag Status:	Flagged	

Thank you for submitting this additional information. Doctor Wolff will send an official response soon.

Best regards, Brent Morse

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

From: IACUC <iacuc@ucsd.edu>
Sent: Monday, January 14, 2019 3:18 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Brown, Sandra <sandrabrown@ucsd.edu>; Richter, Philip <pjrichter@ucsd.edu>;
(b) (6)
McMahill, Angela <amcmahill@ucsd.edu>; Anderson-Vicino, Kristen <kca002@ucsd.edu>
Subject: Response from University of California, San Diego

Dear Dr. Wolff,

Please find attached correspondence from Sandra A. Brown, Vice Chancellor for Research at the University of California, San Diego.

Regards,

Kristen

Kristen C. Anderson-Vicino, MS, CPIA, LATG Director, IACUC Office Research Compliance and Integrity Office of the Vice Chancellor for Research | UC San Diego | 9500 Gilman Drive, La Jolla, CA 92093-0071 http://blink.ucsd.edu/sponsor/iacuc/ The information contained in this email message is privileged and confidential information intended for the use of the addressee listed above. If you are neither the intended recipient or the employee or agent responsible for delivering this information to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or taking any action in reliance on the content of this information is strictly prohibited.

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December 26, 2018

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

> FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

Re: Animal Welfare Assurance A3033-01 [OLAW Case 2A]

Dr. Sandra A. Brown Vice Chancellor for Research Affairs University of California-San Diego 9500 Gilman Drive, LaJolla, CA 92093-0043

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 21, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- San Diego, following up on an initial telephone report on December 14, 2018. According to the information provided, OLAW understands that two rabbits died and four required euthanasia after being injected with a higher dose of barium chloride than approved in the protocol. This occurred due to a miscalculation of the dose.

The corrective actions consisted of the Principal Investigator implementing measures to prevent recurrence.

In order for OLAW to assess the appropriateness of the corrective actions, please outline in detail what was proposed to prevent miscalculation of drug dosages. Please provide this information by **January 14**, **2019**.

Sincerely,

(b) (6)

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

cc: IACUC Chair

Robert Gibbens, D.V.M., USDA-APHIS-AC

(b) (6)

(b) (6)

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Wednesday, December 26, 2018 6:43 AM
То:	IACUC
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Letter from University of California, San Diego

Thank you for this report. We will send a response soon.

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

From: IACUC <iacuc@ucsd.edu> Sent: Friday, December 21, 2018 8:27 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: Brown, Sandra <sandrabrown@ucsd.edu>; Richter, Philip <pjrichter@ucsd.edu>; (b) (6) (b) (6) McMahill, Angela <amcmahill@ucsd.edu>; Anderson-Vicino, Kristen <kca002@ucsd.edu> Subject: Letter from University of California, San Diego

Dear Dr. Wolff,

Please find attached correspondence from Sandra A. Brown, Vice Chancellor for Research at the University of California, San Diego.

Regards,

Kristen

Kristen C. Anderson-Vicino, MS, CPIA, LATG Director, IACUC Office Research Compliance and Integrity Office of the Vice Chancellor for Research | UC San Diego | 9500 Gilman Drive, La Jolla, CA 92093-0071 http://blink.ucsd.edu/sponsor/iacuc/

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16033-214



Initial Report of Noncompliance

By: and

Date: 12/14/18

Time: 1:30

Name of Person reporting: KRISTEN Addison Betting Vicino Telephone #: Fax #: Email:

Name of Institution: U of Cal - San Diego Assurance number: <u>A 3033</u>

Did incident involve PHS funded activity?

Funding component:

Was funding component contacted (if necessary):

What happened? Barimel Robelts given drug + 2 died . Concentration too high due to calculation error

Species involved: Rolchit Personnel involved: Dates and times: Animal deaths: 2 dired, 4 entropyed

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

Made new batch

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____