



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
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

July 25, 2017

Re: Animal Welfare Assurance
A3033-01 [OLAW Case 1W]

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

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 21, 2017 letter reporting the suspension of an animal activity at the University of California- San Diego, following up on an initial telephone report on July 18, 2017. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that a Principal Investigator (PI) euthanized neonatal mouse pups by an unapproved method. The pups were needed as embryos but were unintentionally born because the dams were not being monitored.

The corrective actions consisted of the IACUC requiring the PI to obtain a letter of support from the Department Chairperson endorsing reinstatement of animal use privileges, a description of oversight of animal activities, and if acceptable to the IACUC a new protocol outlining monitoring of the pregnant mice and approved euthanasia in case of unintended births.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incident was serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at the University of California- San Diego are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

A3033

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SANTA BARBARA • SANTA CRUZ

SANDRA A. BROWN, PH.D.
VICE CHANCELLOR FOR RESEARCH
INSTITUTIONAL OFFICIAL
9500 GILMAN DRIVE MC 0043
LA JOLLA CA. 92093-0043

July 21, 2017

Axel Wolff, MS, DVM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Wolff,

Per PHS Policy IV.F.3, I am writing to advise you of an incidence of serious noncompliance and subsequent suspension of a UC San Diego Principal Investigator's mouse protocol. The suspension was due to the Principal Investigator's description of an unapproved method to euthanize neonatal mouse pups, which were unintentionally born as a result of lack of monitoring of his pregnant female mice used to create mouse embryonic fibroblasts.

Before the suspension may be lifted, the Principal Investigator must provide a letter of support from his Department Chairperson endorsing his reinstatement of animal use privileges and detailing oversight measures that will be enacted to prevent further violations of animal care standards. If the IACUC receives and accepts such an assurance, he will be allowed to submit a new protocol to the IACUC to describe his proposed research and address specifically how he will prevent accidental births from occurring if he intends to generate mouse embryonic fibroblasts. He will also need to include an AVMA-approved method of euthanasia of the neonatal pups in the event that his plan of preventing live births fails.

The Principal Investigator does not receive any funding support from PHS. If you have any questions, please contact me at Phone Number or sandrabrown@ucsd.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sandra A. Brown'.

Sandra A. Brown, PhD
Vice Chancellor for Research
IACUC Institutional Official
Assurance number: A3033-1 or D16-00020

cc: Philip Richter, DVM, PhD, Director, Animal Care Program
Secondary Individual Executive Director, Research Compliance and Integrity
IACUC Member Director, IACUC Office
Michael Gorman PhD, Chair, UCSD IACUC
IACUC Member Vice Chair, UCSD IACUC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 25, 2017 1:23 PM
To: Secondary Individual
Subject: RE: Letter from UC San Diego

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

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: Secondary Individual [mailto:Secondary Individual@ucsd.edu]
Sent: Tuesday, July 25, 2017 1:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Brown, Sandra <sandrabrown@ucsd.edu>; IACUC <iacuc@ucsd.edu>; Richter, Philip <pjrichter@ucsd.edu>; Secondary Individual @ucsd.edu; Secondary Individual @ucsd.edu; Gorman, Michael <mgorman@ucsd.edu>; Secondary Individual @ucsd.edu; Secondary Individual @ucsd.edu
Subject: Letter from UC San Diego

The attached letter is forwarded on behalf of Sandra A Brown, Vice Chancellor for Research. Please let us know if you have questions.

Secondary individual
Phone Number
Secondary Individual@ucsd.edu



Initial Report of Noncompliance

By: *AS*

Date: *7/18/17*

Time: *10:45*

Name of Person reporting: *Secondary Individual*

Telephone #: *Phone Number*

Fax #:

Email:

Name of Institution: *U of California San Diego*

Assurance number: *A 3033*

Did incident involve PHS funded activity? *No*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Pregnant mice not monitored & pups born. All changed
not on protocol, killed by blunt force trauma*

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths:

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

Suspend protocol, terminate

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____