

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

May 9, 2019

Re: Animal Welfare Assurance A3344-01 [OLAW Case E]

Sadiq Shah, Ph.D.
Associate Vice President for Research,
Innovation and Economic Development
California State Polytechnic University-Pomona
3801 West Temple Avenue
Pomona, CA 91768

Dear Dr. Shah,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 7, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at California State Polytechnic University- Pomona, following up on an initial report on April 25, 2019. According to the information provided, OLAW understands that due to cold external temperature, 30 tilapia fish died. The matter was not reported to the Attending Veterinarian or Institutional Animal Care and Use Committee (IACUC). Furthermore, it was determined that the Principal Investigator (PI) maintained a satellite facility at an elementary school and had not notified the IACUC. The goldfish housed at the school were not listed on the protocol. Due to not knowing about this facility, semiannual reviews were not conducted by the IACUC.

The corrective actions consisted of suspending the protocol, adding water heaters to the fish tanks, counseling the PI, requiring a new protocol which is to include the satellite facility, and requiring a facility inspection before approving the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



May 7, 2019

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

Dear Dr. Morse:

California Polytechnic State University Pomona (Cal Poly Pomona), in accordance with Assurance A3344-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident resulting in the death of tilapia used for an aquaponics project, an incident that was not reported to the IACUC nor the Attending Veterinarian (AV) in a Principal Investigator's (PI) animal study protocol, entitled "Aquaponics." This incident was first reported to OLAW, on April 25, 2019 via email by (b) (6)

Office of Research Innovation and Economic Development.

On April 8, 2019, while conducting semiannual inspections, the IACUC discovered that there had been an incident resulting in the death of tilapia on January 3rd and 4th, 2019 on campus that was not reported. The PI sent a summary of the incident to the Compliance office on April 22, 2019. The cold winter Southern California experienced this year caused the water temperature to drop to freezing temperatures for the tilapia.

After further investigations, it was discovered that the PI had a satellite facility at a local elementary school which was not reported to the IACUC and therefore, was not reviewed or inspected by the IACUC. Additionally, the PI maintained goldfish in the water tanks, goldfish are not listed under species to be used on their protocol. This protocol is not federally funded.

To address the situation, the PI was invited to answer questions at the subsequent IACUC meeting. During the meeting, the PI took responsibility for the noncompliance and assured the committee that they will take the necessary steps to prevent such an event from reoccurring. The IACUC determined that there was much to be done to assist PI and made the decision to suspend the protocol until procedures to improve animal welfare are in place.

The key issues that led to the decision include the following:

- 1. Failure to report deaths to the Attending Veterinarian and the IACUC
- 2. Use of a species not listed on your protocol

3. Discovery of a second facility off campus that was not reported to the IACUC.

The following corrective action plan was implemented after the incident:

- 1. The PI submitted a summary to the Compliance Office on April 22, 2019, the PI willingly answered the committee's questions during an IACUC meeting.
- 2. The PI described corrective measures that had been implemented after the incident to prevent recurrence. The measures included adding aquarium water heaters to the fish tanks.
- The IACUC requested that the PI consult with the AV to improve animal welfare
- 4. The IACUC voted to suspend the protocol pending improvements in animal welfare. The committee met on Wednesday, May 1, 2019. There was a quorum present (10 members with one alternate) and the decision was a majority vote with one abstention.
- 5. A new protocol must be submitted to the IACUC
- 6. The facility must be inspected prior to the new protocol approval
- 7. The protocol must include the satellite facility

At their meeting on May 1, 2019, the IACUC also reviewed and accepted the corrective action plan.

Cal Poly Pomona is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Joanne Sohn, DVM, MPH, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely.

Sadiq Shah, Ph.D.

Associate Vice President

Office of Research, Innovation & Economic Development

Institutional Officer

California State Polytechnic University, Pomona

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, May 09, 2019 8:00 AM

To:

(6)

Cc:

(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Institutional Animal Care and Use Committee Office

Subject:

RE: Final Report of Noncompliance Cal Poly Pomona

Thank you for providing this final report (b) (6)

We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM Director 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.

From: (b) (6)

Sent: Wednesday, May 08, 2019 6:08 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Institutional Animal Care and Use Committee Office <iacuc-office@cpp.edu>

Subject: Final Report of Noncompliance Cal Poly Pomona

Good Afternoon,

I would like to follow up on a preliminary report made by myself on April 25, 2019. Attached you will find the final report from our IO.

Regards,

(b) (6)



Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Friday, April 26, 2019 7:58 AM

To:

(b) (6)

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Preliminary Report of Noncompliance Cal Poly Pomona

Thank you for this preliminary report, (6) (6) We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)

Sent: Thursday, April 25, 2019 8:06 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Institutional Animal Care and Use Committee Office <iacuc-office@cpp.edu>

Subject: Preliminary Report of Noncompliance Cal Poly Pomona

Hello,

I would like to make a preliminary report of an incident at California Polytechnic University Pomona. Below you will find the information we have collected so far. We are currently conducting further investigations and our IACUC will be discussing how to correct or prevent this event from reoccurring at the next meeting (May 1st).

Name of Institution: California State Polytechnic University Pomona

Assurance Number: A3344-01

Description:

During our semiannual inspections, it was discovered that there was an incident that resulted in the death of trout which was not reported to the Attending Veterinarian nor the IACUC by the PI. The PI was instructed to send a summary of the incident to our Compliance Office. Below you will find the summary provided by the PI on.

The aquaponics system in the Lyle center lost 30 tilapia fish and a fresh water algae eater due to the weather condition causing fish tank water temperature drop.

The temperature measured during the day time on January 3rd and 4th (days we lost the fish) was around 48 F which means it probably had been as low as 40 F at

night time. Pomona weather in Winter 2019 became exceptionally cold and only 6 gold fish survived the cold wave. Currently there are 8 gold fish and one algae

eater in the system. We added two aquarium water heaters (HMA 500S electronic controller Titanuim tube with water guard) to the fish tanks on January 7th and

since then the water temperature has been constantly above 60 F.

Timeframe for final report from the IO:

After the committee has had time to discuss that matter, we expect to have the final report submitted by May 15th 2019.

Regards,

(b) (6)



