



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
Bethesda, Maryland 20892-6910
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) 480-3387

February 3, 2020

Re: Animal Welfare Assurance
#A4399-01 (OLAW Case A)

Dr. Debra S. Larson
Institutional Officer
Provost and Vice President for Academic Affairs
California State University – Chico
25 Main Street
Chico, California 95929

Dear Dr. Larson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 31, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at California State University- Chico, following up on an initial report on October 31, 2019. According to the information provided, OLAW understands that bullfrogs were being housed for use in a teaching activity, although the protocol had expired and no renewal had been filed. The animals were not PHS supported.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) directing the investigator to submit a protocol renewal. This was not done therefore the IACUC chair stopped the use of all activities with the frogs and the IACUC subsequently suspended the protocol. A protocol renewal was submitted by the Principal Investigator, the PI was counseled, the renewed protocol was approved by the IACUC, and the frog facility was inspected by the IACUC. Institutional animal handling practices were reviewed, all protocols were checked to ensure they were current and approved, animal users will be reminded of IACUC requirements, new animal users will receive an animal welfare orientation, the IACUC will monitor protocol expiration dates and send out reminders, and the IACUC will develop a plan to communicate animal care and use information to all investigators.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



January 31, 2020

emailed: olawdco@od.nih.gov

Director, 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 Director,

In accordance with Assurance A4399-01 and PHS Policy IV.F.3, California State University, Chico provides this final report of noncompliance regarding the housing and planned use of *Rana catesbeiana* (American bullfrog) for instruction and laboratory experimentation, activities for which there was an expired protocol on file and no renewal application was submitted or approved. This incident was first reported to your office via email on October 31, 2019 by the Chico State University Institutional Officer and University Provost, Dr. Debra Larson.

In the course of a conversation with a faculty member in early May 2019, IACUC administrative staff learned that frogs were being housed in one of the science laboratories and immediately notified the IACUC chair. After further inquiry, the IACUC chair was advised that the professor housing the frogs planned to use them as part of class instruction for the Biology 416 Laboratory scheduled for fall 2019. IACUC staff later confirmed that the last approved protocol for the frogs expired in 2013 and there was no approved renewal application. Because the frog experimentation is part of class instruction, direct costs of the course are funded from a combination of state funds and tuition and no PHS funds are involved.

On September 6, 2019, the IACUC chair and others met with the faculty member to require the immediate submission of a renewal protocol application to the IACUC. By early October, no updated application had been submitted. On October 14, 2019, the IACUC chair and the college dean visited the laboratory unannounced to confirm the presence of frogs in the room and counted 11 frogs. The chair immediately halted the use of the frogs including euthanasia and preparation for Biology 416 Laboratory experimentation. He also advised that the continued housing and care of the frogs was to be provided in accordance with PHS policy while the committee proceeded with its review. The IACUC chair then called for an urgent meeting and on October 16, 2019, the committee was convened and voted unanimously (one abstention) to suspend the use of the frogs. On October 18, 2019, the chair and IACUC staff met with the professor to advise him of the suspension vote, and on October 21, 2019 the Institutional Officer was formally notified of the suspension.

The following corrective steps and action plan were implemented after the incident:

1. On October 15, 2019, the IACUC received a renewal application from the Principal Investigator.
2. On October 25, 2019 the IACUC held a meeting with the faculty member to review and discuss details of the application and identify outstanding issues to be addressed. On October 30, 2019, the committee approved the revised application.
3. The facility which houses the frogs was inspected again on October 30, 2019, as part of the semi-annual inspection process.
4. (b) (6) where the frogs are housed, conducted a college-wide review of animal handling practices. On December 20, 2019, (b) (6) completed his review and provided updated information and recommendations for corrective actions to the Institutional Officer and to the IACUC Chair, Dr. Patrick Johnson.
5. Dr. Johnson reviewed the college's updated information and concurred with the recommended corrective actions which include the following:
 - a. The college ensured all animal protocols were current and approved.
 - b. Going forward, the college will remind faculty and departments concerning IACUC requirements at least twice yearly.
 - c. Staff working in programs involving animals will be given an orientation to animal welfare as part of their onboarding of new employees.
 - d. The college departments and IACUC will review protocols for expiration dates and send reminders to the faculty. In the absence of a response, (declaration of no use or renewed protocol), IACUC will inspect the facility within one month prior to protocol expiration and either mandate renewal or shut down the instance.
6. The IACUC will work with staff to develop a campus-wide communications plan that ensures the campus community and researchers are aware of animal use requirements, protocol application processes, and roles and responsibilities. The communications plan is to be implemented beginning the upcoming fall semester.

California State University, Chico is committed to protecting the welfare of animals used in instruction and research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Patrick Johnson, PhD, IACUC Chair (psjohnson@csuchico.edu).

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Debra S. Larson, PhD
Institutional Officer
Provost and Vice President for Academic Affairs

cc:

(b) (6)

Patrick Johnson, Chair, IRB & IACUC, Assistant Professor, Department of Psychology,

(b) (6)

Annabel Grimm, Director, Audits & Continuous Improvement

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, January 31, 2020 1:20 PM
To: Academic Affairs; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Debra S Larson; (b) (6) Patrick S Johnson; (b) (6) Annabel Grimm; (b) (6)
Subject: RE: Chico State Final Report

Thank you for this report. 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: Academic Affairs [mailto:academicaaffairs@csuchico.edu]
Sent: Friday, January 31, 2020 12:50 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Debra S Larson <dslarson@csuchico.edu>; (b) (6) Patrick S Johnson <psjohnson@csuchico.edu>; (b) (6) Annabel Grimm <agrimm@csuchico.edu>; (b) (6)
Subject: Chico State Final Report

Good morning,

Attached please find Chico State's final report of noncompliance regarding the housing and planned use of *Rana catesbeiana* (American bullfrog) for instruction and laboratory experimentation.

We would appreciate a confirmation of receipt of this report.

Thank you.

(b) (6)

(b) (6)

Legacy: Making a difference today with tomorrow in mind

Pronouns: She/Her

CALIFORNIA STATE UNIVERSITY, CHICO
Chico, California 95929-0110
Provost and Vice President for Academic Affairs
Ph: 530-898-6101

December 30, 2019

Director, 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
olawdco@mail.nih.gov

Dear Director,

On October 31, 2019 and in accordance with Assurance A4399-01 and PHS Policy IV.F.3, California State University, Chico submitted the preliminary report of noncompliance regarding the housing and planned use of *Rana catesbeiana* (American bullfrog) for instruction and laboratory experimentation, activities for which there was an expired protocol on file. This letter is to notify you of our revised date of January 31, 2020 for submission of the final report.

Should you have any questions in this regard, please contact Patrick Johnson, PhD, IACUC Chair at (b) (6) or ps.johnson@csuchico.edu.
(b) (6)

Debra S. Larson
Institutional Officer
Provost and Vice President for Academic Affairs

cc:

(b) (6)

Patrick Johnson, Chair, IRB & IACUC, Assistant Professor (Psychology)
Annabel Grimm, Director, Audits & Continuous Improvement

The California State University

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 02, 2020 7:40 AM
To: Debra S Larson; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Patrick S Johnson
Subject: RE: extension on final report

Thank you for this update Dr. Larson. We look forward to receiving the final report by the end of January 2020.

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: Debra S Larson [mailto:dslarson@csuchico.edu]
Sent: Tuesday, December 31, 2019 6:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Patrick S Johnson <psjohnson@csuchico.edu>
Subject: extension on final report

Please find the attached memo. We intend to file our final report by the end of January regarding an earlier notification of possible improper protocols.

Thank you.

Debra Larson, PhD
Provost and Vice President of Academic Affairs
Professor of Civil Engineering
Chico State University
Kendall Hall, (b) (4)
Chico, CA 95929-0110
Office: (b) (6)

California State University, Chico
 Chico, California 95929-0110
 Provost and Vice President for Academic Affairs
 530-898-6101
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October 31, 2019

Director, 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

emailed: olawdco@mail.nih.gov



Director,

In accordance with Assurance **A4399-01** and PHS Policy IV.F.3, California State University, Chico provides this preliminary report of noncompliance regarding the housing and planned use of *Rana catesbeiana* (American bullfrog) for instruction and laboratory experimentation, activities for which there is an expired protocol on file.

In the course of a conversation with a faculty member in early May 2019, IACUC administrative staff learned that frogs were being housed in one of the science laboratories and immediately notified the IACUC chair. After further inquiry, the IACUC chair was advised that the professor housing the frogs planned to use them as part of class instruction for the Biology ^{(b) (4)} Vertebrate Physiology Laboratory scheduled for fall 2019. IACUC staff later confirmed that the last approved protocol for the frogs expired in 2013 and there was no approved renewal application. Because the frog experimentation is part of class instruction, direct costs of the course are funded from a combination of state funds and tuition and no PHS funds are involved.

On September 6, 2019, the IACUC chair and others met with the faculty member to require the immediate submission of a renewal protocol application to the IACUC. By early October no updated application had been submitted. On October 14, 2019, the IACUC chair and the college dean visited the laboratory unannounced to confirm the presence of frogs in the room and counted 11 frogs. The IACUC chair immediately halted the use of the frogs including euthanasia and preparation for Biology ^{(b) (4)} Laboratory experimentation. He also advised that the continued housing and care of the frogs was to be provided in accordance with PHS policy while the committee proceeded with its review. The IACUC chair then called for an urgent meeting and on October 16, 2019, the committee was convened and voted unanimously (one abstention) to suspend the use of the frogs. On October 18, 2019, the chair and IACUC staff met with the professor to advise him of the suspension vote, and on October 21, 2019 the Institutional Officer was formally notified of the suspension.

Over the next few days, the IACUC members received and reviewed a renewal application but determined that it lacked adequate detail and revision would be required. The IACUC's continued review is in progress as of this writing.

The following preliminary corrective action plan has been implemented after the incident:

1. On October 16, 2019, the IACUC voted unanimously to suspend the use of the frogs. Later that day, the IACUC received a renewal application for use of the frogs but determined that it lacked adequate detail.
2. On October 18, 2019 the IACUC chair and staff met with the professor to advise him of the suspension vote and encouraged him to provide a thorough response to the IACUC questions and suggestions.
3. On October 21, 2019, the Institutional Officer was notified of the suspension.
4. On October 25, 2019 the IACUC held a meeting with the faculty member to discuss details of the application and identify outstanding issues to be addressed.
5. The facility which houses the frogs was inspected again on October 30, 2019, as part of the semi-annual inspection process.
6. The committee will review the revised renewal application and make any further recommendations at that time.
7. Estimated time frame for submission of final report is December 31, 2019.

Chico State University is committed to protecting the welfare of animals used in instruction and research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Patrick Johnson, PhD, IACUC Chair at (b) (6) or psjohnson@csuchico.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Debra S. Larson
Institutional Officer
Provost and Vice President for Academic Affairs

cc:

(b) (6)

Patrick Johnson, Chair, IRB & IACUC, Assistant Professor (Psychology)
Annabel Grimm, Director, Audits & Continuous Improvement

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 1, 2019 7:04 AM
To: Academic Affairs
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: CSU, Chico Preliminary Report

Thank you for this preliminary report, (b) (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) On Behalf Of Academic Affairs
Sent: Thursday, October 31, 2019 11:51 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Debra S Larson <dslarson@csuchico.edu>; (b) (6)
(b) (6) Patrick S Johnson
(b) (6) Annabel Grimm <agrimm@csuchico.edu>
Subject: CSU, Chico Preliminary Report

Good morning,

Attached please find California State University, Chico's preliminary report of noncompliance regarding the housing and planned use of *Rana catesbeiana*.

Please confirm receipt of this report by responding to this email.

Thank you.

(b) (6)

